ThemenCheck Medizin

Extract of HTA report

Social isolation and loneliness in the elderly[1]

What measures can prevent or counteract social isolation?

Health technology assessment commissioned by IQWiG

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[1] Translation of Chapters 1 to 9 of the HTA report HT20-03 *Soziale Isolation und Einsamkeit im Alter: Welche Maßnahmen können einer sozialen Isolation vorbeugen oder entgegenwirken?* (Version 1.0; Status: 17 November 2022 [German original], 21.07.2023 [English translation]). Please note: This document was translated by an external translator and is provided as a service by IQWiG to English-language readers.

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IQWiG coordinated the project, conducted the literature search for the domains “Benefit assessment“ and “Health economic evaluation”, and prepared the easily understandable summary (HTA compact).

Keywords: Social Isolation, Aged, Benefit Assessment, Systematic Review, Technology Assessment – Biomedical

According to §139b (3) No. 2 of Social Code Book (SGB) V, Statutory Health Insurance, external experts who are involved in the Institute's research commissions must disclose "all connections to interest groups and contract organizations, particularly in the pharmaceutical and medical devices industries, including details on the type and amount of any remuneration received". The Institute received the completed *Form for disclosure of potential conflicts of interest* from each external expert. The information provided was reviewed by a Committee of the Institute specifically established to assess conflicts of interests. The information on conflicts of interest provided by the external experts and external reviewers is presented in Chapter A11 of the full report. No conflicts of interest were detected that could endanger professional independence with regard to the work on the present commission.

Publisher's comment

What is the background of the HTA report?

Insured persons and other interested individuals are invited to propose topics for the assessment of medical procedures and technologies through "ThemenCheck Medizin" (Topic Check Medicine) to the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG). The assessment is done in the form of a Health Technology Assessment (HTA) report. HTA reports include an assessment of medical benefit and health economics as well as an investigation of ethical, social, legal, and organizational aspects of a technology.

In a 2-step selection procedure, which also involves the public, up to 5 new topics are selected each year from among all submitted proposals. According to the legal mandate, these topics are supposed to be of particular relevance to patients [1]. IQWiG then commissions external teams of scientists to investigate the topics in accordance with IQWiG methods, and it publishes the HTA reports.

In October 2020, IQWiG commissioned a team of scientists under the leadership of Hamburg-Eppendorf University Hospital to investigate the selected topic "HT20-03: Social isolation and loneliness in the elderly: Which interventions can prevent or reduce social isolation?" The team consisted of methodologists experienced in generating HTA reports, experts with knowledge and experience in health economic, ethical, social, legal, and organizational topics as well as a general practitioner.

Why is the HTA report important?

Social isolation is an objectively measurable condition of being isolated and lacking social integration (operationalized via structural conditions such as "living in a 1-person household" or the quantity of social contacts), while loneliness describes an emotion; hence, the latter condition is a subjectively perceived one which may be experienced independently of the number and quality of social contacts.

In Germany, about every 5th person lives in a 1-person household, and about 2/3 of them are 65 years of age or older [2]. However, the fact that they live in a more isolated manner does not necessarily mean that these persons feel lonely. The feeling of loneliness affects all age groups and a total of about 10% of all adults [3,4]. Often, social isolation and loneliness coincide, and they may mutually exacerbate each other.

At a higher age, risk factors for social isolation and loneliness increase, e.g. due to the loss of a partner, deteriorating hearing and visual acuity, or reduced mobility. While social isolation

and loneliness do not represent classic disorders, they are associated with an increased risk of certain disorders such as depression and anxiety, cognitive impairment, hypertension, and stroke.

Concerns of those proposing the topic

A member of the public asked whether effective interventions exist for preventing and reducing social isolation, arguing that social isolation in the elderly is becoming an increasingly widespread problem and leads to both psychological and physical impairments.

Objective of the HTA report

Given the proposed topic of interest, the commissioned team of experts investigated from the different perspectives of an HTA report whether persons who are affected by social isolation and loneliness or exhibit risk factors for these conditions can expect to benefit from interventions for the reduction or prevention of social isolation. This would be the case if it was demonstrated that the interventions improve social participation or reduce the occurrence of mental disorders such as depression. A benefit would also exist if health-related quality of life was favourably influenced to an extent which can be perceived by the affected people.

Which questions are answered – and which are not?

The external experts under the leadership of Hamburg-Eppendorf University Hospital found a total of 14 randomized controlled trials (RCTs). Among these RCTs, 6 pursued a preventive approach with the objective of preventing social isolation and loneliness in persons aged 60 years and older. Eight studies had a “therapeutic” approach for counteracting social isolation and loneliness in persons aged 65 years and older. Interventions ranged from volunteer visits to participants’ own, familiar living environment to training courses given by volunteers regarding the use of tablets and professional-led group programmes with a focus on exercise, leisure activities, or the strengthening of social skills. These interventions were compared to no intervention or a waiting control group or standard care (e.g. support regarding everyday activities). One study investigating home visits to recently widowed people used a control group which received, alongside standard care, a minimal intervention in the form of being offered a brochure on the topic of grief.

On the basis of the available studies, it was impossible to draw an unequivocal conclusion regarding which interventions may help to prevent or reduce social isolation and loneliness in the elderly. In part, this was due to the studies exhibiting methodological limitations and not investigating adverse events. For some interventions, however, favourable effects were found. A 7-month Chinese programme involving professional-led group work for increasing social skills via self-reflection and for promoting communication with others led to elderly persons whose adult children had moved out of their household feeling better socially

supported afterwards. In elderly persons who had already been socially isolated and lonely, a 1-year US programme involving weekly visits by same-age volunteers reduced anxiety symptoms, and a 6-week Canadian programme with weekly visits by volunteer students increased life satisfaction. A 3-month professional-led group programme in Finland likewise showed favourable effects. In this programme, which offered a choice of therapeutic writing and psychotherapy, sports and exercise as well as arts and stimulating activities, the self-reported health status improved and mortality decreased over a period of 2 years.

For the interventions with home visits and psychosocial group sessions, which showed partially favourable effects, the intervention costs were estimated for the German healthcare context. Accordingly, a programme involving 10 to 12 home visits by volunteers who are trained and supported by a professional costs between €250 and €400 per person. A 3-month programme with professional-led weekly group activities with exercise, arts, or therapeutic writing would cost slightly over €400 per person.

Furthermore, each of these 2 interventions were examined in the context of an accompanying health economic study. While a cost-utility analysis showed home visits by volunteers to be a potentially cost-effective measure in the Dutch healthcare system when compared with standard care supplemented by an information brochure, the study did not show a significant between-group difference regarding benefits or costs. A comparative cost analysis from Finland showed that the professional-led group programme led to subsequently lower utilization of health services and hence to cost savings which were higher than the total cost for the intervention.

On the basis of scoping literature searches, conversations with affected people, and a stakeholder discussion, ethical, social, legal, and organizational aspects related to the phenomenon of “social isolation and loneliness in the elderly” were identified. The external experts particularly focused on questions regarding barriers to implementation and the intervention design needed to ensure that they are accepted by affected people and can exhibit a potential effect.

First, efforts must be taken to reach the relevant target group with the programmes. Particularly the “quiet elderly” are difficult to locate; service offerings are often overlooked, or a feeling of shame exists since socially isolated persons are at risk of becoming stigmatized quickly. Often, affected people also fear becoming dependent and hence lose their autonomy as a result of utilizing services. The experts conclude that it is important to tailor interventions to local needs, involve affected people in their design, and connect services to interfaces such as general practitioner offices or mobile nursing services. Additional factors to promote successful implementation can be a low-threshold nature of services and consideration of sociocultural and socioeconomic barriers. To ensure sustainability and continuity, the services should be planned and funded for the long term.

From a legal perspective, the external experts see various opportunities to tie interventions to social security systems. This particularly includes social welfare (Social Code Book, SGB XII), which covers assistance to the elderly, but also statutory health insurance (SGB V) with regard to prevention and health promotion.

In terms of content, the interventions should be designed with particular focus on the preferences of affected people. The interventions must be attractive and enjoyable. The top priority of affected people is to have an opportunity to establish social contacts and to communicate. Components may include group activities and active elements such as sports activities or excursions. Using trained volunteers who may themselves be affected people and are therefore familiar with needs and preferences is an option to create a natural atmosphere.

What's the next step?

A Canadian systematic review [5] published in October 2022 demonstrates that the topic of "social isolation and loneliness in the elderly" is more pressing than ever and of international interest. In the Canadian publication, the research question is worded a bit more comprehensively and includes, e.g., measures for nursing home residents. Its conclusion is similar to that of the HTA report: favourable effects were found for some interventions – but due to heterogeneity and the low number of studies, they are to be interpreted with caution.

In view of this conclusion and the challenges posed by an ageing society, it is imperative to develop valid concepts for the prevention and reduction of social isolation and loneliness in the elderly and to perform studies investigating their benefit and harm. These studies should be of long duration to also allow investigating longer-term effects of the interventions, e.g. on physical health and mortality. Concept development may be informed by the prior work done in the context of studies as well as this HTA report. For instance, programmes with home visits involving volunteers and professional-led psychosocial group sessions represent promising approaches which might be integrated and evaluated in needs-adapted and context-adapted concepts for the prevention and reduction of social isolation and loneliness in the elderly.

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HTA key statements

Research questions of the HTA report

The aims of this investigation are to

- assess the benefit of interventions intended to favourably influence outcomes relevant for the target group by (a) resolving or (b) preventing social isolation or loneliness in comparison with care provided without these interventions or with minimal interventions, each (1) in persons aged 65 years and older who meet an objective criterion of social isolation and who subjectively suffer from loneliness or (2) in persons aged 60 years and older who exhibit risk factors for social isolation and loneliness,

- assess the cost (intervention cost) of interventions aiming to favourably influence target-group-relevant outcomes by (a) resolving or (b) preventing social isolation or loneliness, each (1) in persons aged 65 years and older who meet an objective criterion of social isolation and who subjectively suffer from loneliness or (2) in persons aged 60 years and older who exhibit risk factors for social isolation and loneliness,

- assess the cost effectiveness of interventions aiming to favourably influence target-group-relevant outcomes by (a) resolving or (b) preventing social isolation or loneliness in comparison with care provided without these interventions or with minimal interventions, each (1) in persons aged 65 years and older who either meet an objective criterion of social isolation and who subjectively suffer from loneliness or (2) in persons aged 60 years and older who exhibit risk factors for social isolation and loneliness, and

- review ethical, social, legal, and organizational aspects associated with the medical interventions.

Conclusion of the HTA report

For the benefit assessment, 14 randomized controlled trials (RCTs) investigating interventions intended to prevent and treat social isolation and loneliness were analysed. Six studies focused on the evaluation of preventive interventions, while 8 studies investigated interventions with a therapeutic approach. Interventions implemented by volunteers or healthcare or social professionals existed both in the group of prevention studies and the group of therapeutic studies. The examined interventions are very heterogeneous: volunteer visits in private homes, telephone calls/friendships with volunteers, professional-led group programmes, technology training by volunteers, and a Tai Chi Qigong intervention in combination with volunteer health guides. The described interventions had a duration of 1.5

to 12 months. In the majority of studies, the mean age of the study population was between 70 and 80 years. In almost all studies, over 50% of the study population was female, and 1 study was even restricted to women only.

The risk of bias of all included studies was classified as high already at the study level.

None of the included studies investigated adverse effects of the intervention, but all other prespecified outcomes were reported. The number of investigated outcomes ranged from 1 to 16. Four studies reported no statistically significant changes in favour of the intervention for any of their observed outcomes. Two studies reported statistically significant differences in favour of the intervention for the sole investigated outcome. The remaining 8 studies present mixed results.

Out of a total of 10 statistically significant results found in the prevention studies, only 1 outcome was shown to have relevance. Findings are similar for therapeutic studies: out of 9 statistically significant results on different outcomes, 4 were shown to be relevant.

All things considered, the favourable results which were seen in some areas are difficult to interpret due to high risk of bias, unclear power of most studies included in the benefit assessment, and poor reporting quality of the evaluation of complex interventions. From the evidence available for the benefit assessment, no proof or indications can be derived of a certain type of intervention being effective for preventing, reducing, or managing social isolation and loneliness in elderly people. At the same time, however, it is impossible to conclusively determine the investigated interventions to be ineffective because hints of benefit can be derived for 2 types of interventions (volunteer visits in participants' private homes and professional-led group programmes) and 5 outcomes (social support, mortality, anxiety, self-reported health status, and life satisfaction). For instance, hints were found for programmes involving volunteer visits to socially isolated and lonely persons at minimum increasing life satisfaction or reducing anxiety. Further, there is a hint of professional-led social group work increasing social support in persons at risk of isolation and loneliness. There are hints of professional-led group services reducing mortality and improving self-reported health in socially isolated, lonely persons.

The health economic assessment investigates (a) costs associated with the technology (intervention costs) and (b) comparative health economic studies. The systematic searches found only 2 health economic publications. These are from 2 studies with therapeutic intention which were also included in the benefit assessment. One study published a cost-utility analysis for the volunteer-implemented widow-to-widow programme, and the second performed a cost-cost comparison between the intervention and control groups for a professionally implemented psychosocial group intervention. The intervention costs calculated as part of study implementation amount to currency-converted and inflation-

adjusted €574 per person for volunteer home visits. The difference in cost compared with the control group (standard care and information brochure) of currency-converted and inflation-adjusted €-218 was not statistically significant. For the professionally implemented psychosocial group intervention, there was a currency-converted and inflation-adjusted significant cost difference in the amount of €1127 in favour of the intervention group (control group: no intervention). However, this does not include the costs of the group programme reported in the publication, equalling currency-converted and inflation-adjusted €1053 per person. No cost-outcome ratio was determined for the measured outcomes.

Furthermore, when interpreting the health economic results, the different study types, methodological deficits, and the different underlying health systems with corresponding variation in the involved cost parameters must be taken into account. Therefore, no unequivocal conclusions can be drawn regarding the cost-effectiveness of certain forms of interventions for preventing or reducing social isolation and loneliness in elderly people, particularly not for the German healthcare context.

On the basis of the information provided in the 2 publications, the potential intervention costs were calculated for the German context. For volunteer visits (organization and implementation of 10 to 12 home visits per participant), they equalled €246 to €403 per participant, depending on whether supervision was involved. For the professional-led 3-month group programme, mean intervention costs of €434 per participant were calculated.

They were calculated in light of the results of the analyses from ethical, social, organizational, and legal perspectives are based on the systematic analysis of the discussion sections of the publications included in the benefit assessment, other relevant publications from the scoping literature searches, interviews of affected people, and the discussion in a stakeholder workshop. Interventions combating social isolation and loneliness are generally associated with positive connotations, with their “benefit” not necessarily being defined by health-related outcomes but contact with other people being perceived as a success in itself. Social contact is associated in particular with joy, fun, and higher quality of life, and favourable effects on health are expected as a result. The idea that services must be tailored to needs has been repeatedly emphasized. Needs orientation is related, on the one hand, to specific characteristics of the target group, such as reachability (e.g. “quiet elderly”), sociocultural makeup, special triggers of social isolation and loneliness (e.g. loss of close relatives), or disease-related barriers. Another topic area is the services’ contents. Different mechanisms of action have been discussed: community-building stimuli through group activities, the unburdening, connecting function of confiding in others, particularly people in similar situations, and the targeted reduction of individual psychological barriers and strengthening of self-efficacy in more therapy-oriented settings. Participation of the target group in developing services is believed to promote acceptance and ensure both the authenticity of

encounters and fit of intervention content to interests. Otherwise, interventions may exhibit a high dropout rate, rendering them inefficient. On the other hand, differentiating between preventive and therapeutic interventions is deemed of little use, whereas focusing on the severity of impairment would be more useful.

The implementation of interventions must take into account both mental barriers and technical and organizational aspects. The removal of mental barriers can be supported, e.g. by multi-step services, where an initial trust-building phase is followed by a phase with more extensive contacts. Another essential factor in this context is the sustainability of services, which was identified as a critical ethical criterion. Technical and organizational aspects include the reachability of services by (public) transport or any driving services, taking into account any costs incurred, or low-threshold access to services without complex application procedures. Particular challenges result from the large regional variations in services (urban-rural gap), the population being heterogeneous in terms of sociocultural and socioeconomic background, and the difficulties associated with reaching particularly vulnerable population groups. Therefore, different strategies should be followed for the advertising of services. Alongside public communication via local media, bulletin boards, or flyers, which tend to attract the participation of relatively “active” seniors, interventions should employ targeted, if necessary, outreach strategies, e.g. involving general practitioners’ offices, mobile nursing or social services or pharmacies in order to reach more isolated clients who might be in particular need.

Further organizational aspects are infrastructure and staff. Group-based services might take place, e.g. in municipal or neighbourhood centres, elderly assistance facilities, day-care facilities for seniors, libraries, or sports facilities. Services to combat social isolation and loneliness are implemented by both trained professionals, e.g. social workers or nurses, and by volunteers who are typically laypersons with regard to their social work or nursing expertise. With support offerings which are based on reciprocity, members of the target group become active service providers as well. One challenge in this context is ensuring that all involved parties possess adequate qualifications, which are not limited to knowledge of the intervention itself, but also comprise skills such as discussion moderation, group leadership, social skills, and the handling of vulnerable groups. The recruitment and qualification of volunteers, in particular, can quickly become a hurdle to the implementation of interventions, particularly in regions which tend to be socioeconomically disadvantaged.

From a social law perspective, several options for integrating interventions to combat social isolation and loneliness are already available. Assistance for the elderly, for instance, already offers various interventions to combat social isolation and loneliness in the elderly, e.g. volunteer visiting services and professional-led group programmes. Preventive services may

be covered by health insurance funds because social isolation and loneliness in the elderly increases the risk of disease, particularly mental disorders.

Suggestions for the future also include selective contracts as per Section 149a SGB V with long-term care insurance, municipalities, and welfare institutions, which also aim to better integrate the prevention of social isolation and loneliness in the elderly. It is also conceivable to enshrine care and case management in standard care under health insurance law as well as to enshrine a subjective public right to aid in case of social isolation and loneliness in elderly assistance law. This could provide affected people with legally enforceable rights to services even beyond the existing services. For this purpose, elderly assistance law would need to be restructured in such a way that it includes a catalogue of services listing favourably evaluated interventions. This could be modelled after health insurance law, whose concretization concept has implemented the very heterogeneous service prerequisites and service contents in a detailed and subjective legal manner.

Overall conclusion

In summary, the results of this HTA suggest a need for developing and testing valid and needs-adapted concepts for the prevention and reduction of social isolation and loneliness in elderly people on the basis of the variety of prior publications. The MRC framework for the development of complex interventions offers a framework for doing so. For the first step, the development of a theoretical impact model, prior research done in the studies analysed herein can be used, preferably from studies which found advantages of the intervention groups or hints of benefit at least in part of the observed outcomes. Participatory approaches involving relevant stakeholders are recommended for the modelling of interventions, taking into account affected people's preferences and needs as well as service providers' and volunteers' skills and resources. The planning of the implementation strategy and subsequent feasibility study should be informed by requirements and challenges from ethical, social, organizational, and legal perspectives which were determined in Chapter 6 and should additionally comprise a realistic cost estimate which is valid for the German context. Ultimately, effectiveness must be verified in the context of an RCT which focuses equally on (a) process evaluation, (b) the determination of benefit and harm, including based on the outcome parameters determined in consultation with stakeholders, and (c) cost effectiveness. Transparent documentation of all steps ensures the traceability of the approach and the interpretation of results.

Table of contents

List of figures

List of tables

List of abbreviations

Abbreviation	Meaning
ADAS-COG	Alzheimer´s Disease Assessment Scale-Cognitive Subscale
AUA	Angebote zur Unterstützung im Alltag (services for support in everyday life)
CAU	care as usual
CES-D	Center for Epidemiological Studies Depression Scale
CI	confidence interval
CReDECI	Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare, revised
EQ-5D	EuroQol 5-Dimension Utility Score
EUnetHTA	European Network for Health Technology Assessment
GAD-7	Generalized Anxiety Disorder-7 item
GDS	Geriatric Depression Scale
GSE	General Self-Efficacy Scale
HADS	Hospital Anxiety and Depression Scale
HTA	Health Technology Assessment
ICD	International Classification of Diseases
ICG-R	Inventory of Complicated Grief-Revised
INQ	Interpersonal Needs Questionnaire
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
ISEL	Interpersonal Support Evaluation List
LSI-A	Life Satisfaction Index-A
LSNS	Lubben´s Social Network Scale
MMSE	Mini-Mental State Examination
MRC	Medical Research Council
ND	no data
NICE	National Institute for Health and Care Excellence
ONS	Office for National Statistics
PGC	Philadelphia Geriatric Center Morale Scale
PHQ-9	Patient Health Questionnaire 9-item
PRQ	Personal Resource Questionnaire
PSS-FA	Perceived Social Support Scale – Family Members

Abbreviation	Meaning
PSS-FR	Perceived Social Support Scale – Friends
PWS	Psychological Well-Being Score
QALY	quality-adjusted life year
RCT	randomized controlled trial
SCL90	Symptom Checklist 90
SD	standard deviation
SEE	Self-Efficacy for Exercise Scale
SF	Short Form Health Survey
SGB	Sozialgesetzbuch (Social Code Book)
SSRS	Social Support Rating Scale
UCLA-LS	University of California at Los Angeles Loneliness Scale
VAS	visual analogue scale
WTP	willingness to pay

HTA overview

1 Background

1.1 Health policy background and commission

According to Section 139b (5) of Social Code Book V, Statutory Health Insurance (SGB V), statutory health insurance members and other interested people may suggest topics for the scientific assessment of medical interventions and technologies to the Institute for Quality and Efficiency in Health Care (IQWiG). The topics for these health technology assessment (HTA) reports can be submitted on the IQWiG website.

ThemenCheck Medizin aims to promote the involvement of the public in evidence-based medicine and answer questions which are particularly relevant to patient care.

Once yearly and in collaboration with patient representatives and members of the public, IQWiG selects up to 5 topics on which HTA reports are to be prepared. IQWiG then commissions external experts to investigate the research question. The results prepared by the external experts and a publisher's comment by IQWiG are then published in the form of an HTA report.

IQWiG disseminates HTA reports to German institutions, for instance those deciding about healthcare services and structures. The HTA report will be made available to the professional community through the IQWiG website (www.iqwig.de). In addition, a lay summary of the results of the HTA report will be published under the title "HTA compact: The most important points clearly explained". This is done to ensure that the results of HTA reports will impact patient care.

1.2 Medical background

The topic of social isolation and loneliness has increasingly received attention and been the subject of reporting. In 2018, the United Kingdom established a Loneliness Minister, who coordinates strategies and measures to increase citizens' social integration. In their 2018 Coalition Agreement, the German Christian Democrats and Christian Social Union (CDU/CSU) on the one hand and Social Democrats (SPD) on the other stated that they will "...develop strategies and concepts which prevent loneliness in all age groups and combat social isolation" [1].

1.2.1 Terminology

The construct of social isolation has not been clearly defined. It is used to describe a status of objective isolation or lack of social integration which is measured by the size of the social

network and the quantity of social contacts. Some studies use the operationalization of “living in a single-person household” to estimate the extent of the problem “social isolation” in populations and to draw international comparisons [2]. However, the term “social isolation” is often used as a synonym for loneliness. Loneliness describes the subjectively perceived social isolation which results from the individual assessment of the number and quality of contacts and the corresponding unmet need. Feeling alone or lonely therefore does not necessarily mean that the person is actually alone. Likewise, being alone does not necessarily mean that the person feels alone [3]. But indisputably, people who are socially isolated are often also lonely and people who feel lonely are often also socially isolated [4,5].

1.2.2 Pathological significance of social isolation and loneliness

Neither objective social isolation nor subjective loneliness constitutes a disorder with known course of disease and known treatment options. Rather, they represent life situations in which health status and functionality may be impaired due to a lack of social participation. Reduced participation interferes with functional health within the biopsychosocial model [6,7], which in turn increases the risk of disease, particularly in light of complex and unstable contextual conditions (compare effects of the COVID-19 pandemic [8]).

Numerous epidemiological studies show that particularly in elderly people, loneliness and social isolation are associated with an increased risk of hypertension, stroke, depression and anxiety, insomnia, immune stress reactions, cognitive impairment, and the abuse of psychopharmaceuticals [9-11]. Loneliness and social isolation further increase the general mortality risk by a similar amount as smoking, lack of exercise, obesity, and hypertension [5,12-14].

Morbidity, loneliness, and social isolation are known to mutually exacerbate each other, but it remains unclear which aspect is associated with the greatest impact [12,13]. Hawkley and Cacioppo 2010 describe a theoretical explanatory model in which loneliness increases feelings of uncertainty, triggers increased sensitivity for social threats in the environment, and can thereby causes chronic stress. Insecurities in social interactions in turn lead to misinterpretation of behaviours as well as to avoidance behaviours. Morbidity, particularly morbidities associated with shame, e.g. incontinence problems or chronic wounds [15,16], can likewise trigger or increase avoidance behaviour and thereby trigger loneliness and social isolation or increase underlying loneliness and social isolation. Simultaneously, the increase in negative emotions can lead to self-doubt and neglect of other health-promoting behaviours such as physical activity and moderate alcohol consumption [17].

The ICD-10 (International Classification of Diseases and Related Health Problems) merely permits the coding of a person living alone as Z60.2 [18] in order to mark this characteristic as a risk factor. The International Classification of Functionality, Disability and Health (ICF)

Chapter 7 “Interpersonal interactions and relationships”, in contrast, offers a more differentiated classification to operationalize the degree of social integration, the degree of social isolation, and loneliness [6]. However, this classification for determining participation is typically used in diagnostic and therapeutic contexts and less so in research [19].

1.2.3 Epidemiology

Many instruments intended to measure loneliness and social isolation are found in research [20]. The University of California at Los Angeles Loneliness Scale [21] and the De Jong Gierveld Loneliness Scale [22] in various versions, short forms, and translations [23-25] are the most commonly used validated research instruments for measuring loneliness. They ask, for instance, whether respondents miss contact to other people, whether respondents have people in whom they can confide, or whether respondents often feel rejected. The Lubben Network Scale is a validated and established instrument for measuring social isolation [26]. It asks about the absolute frequency of contact with friends and relatives. However, “single-person household” is likewise used as a proxy for social isolation by epidemiological investigations.

Social isolation and loneliness are widespread. An analysis of household size as an indicator for social isolation has shown that 42% of households in Germany are single-person households; in 2018, every 5th person lived in a single-person household [27]. In the age group 65 years and older, this average applied only to men, of whom 19.9% lived alone, while at 47.9%, nearly half of women aged 65 years and older lived alone.

Different results are reported regarding the prevalence of loneliness, depending on the operationalization used in the respective investigations. In a representative panel study from 2007 through 2012, Beutel 2017 calculates a mean prevalence of 10.5% in people aged 35 to 74 years who report loneliness [28]. In 2017, the data from the Socioeconomic Panel (SOEP) showed a prevalence of 9.5% for adult respondents feeling lonely very often or often. In the age group above 60 years, 10.8% felt lonely often or very often [29]. Böger and Huxhold, in contrast, analysed the German Ageing Survey (DEAS) and showed that, in the age group of 70 to 85-year-olds, only 7.1% of respondents suffered from loneliness, while 10% of 40 to 69-year-olds reported the same [30]. For Germany, the SOEP 2017 reports a generally low mean score for loneliness, at 3 on a scale of 0 to 12 (low scores indicating less loneliness). As a result of the pandemic-related contact restrictions in the year 2020, this mean nearly doubled to 5.4 [31]. In Germany, the highest percentages of people affected by loneliness are found in the eastern part of the country, particularly the federal states of Mecklenburg–Western Pomerania and Brandenburg. Especially low loneliness rates are found around the west German metropolitan regions of Munich, Nuremberg, Hamburg, Cologne, and Bonn [2].

Risk factors for social isolation and loneliness in the elderly include, among others, relatives relocating elsewhere, low income, migration status, loss of the partner, divorce, female sex, mobility restrictions, neighbourhoods with low population density, deteriorating hearing and visual acuity, depression, poor general health, multimorbidity [32-34], a limited number of existing social contacts as well as the absence of a strong sense of community in the local area [35-37].

Whether age is to be deemed a risk factor is the subject of debate [2]. In a study with 16 132 participants, Luhmann and Hawkley 2016 showed that age is a negligible factor after controlling for the above risk factors [38]. When that is done, some investigations even show that prevalence decreases with age [28,37,39,40]. But undeniably, the mentioned risk factors for social isolation and loneliness are more common with increasing age, thereby increasing the risk [12]. Likewise, retirement age may be associated with various risk factors for social isolation and loneliness simultaneously because at retirement, social networks and meaningful social roles may disappear, while income typically decreases [41,42].

Factors protecting against social isolation and loneliness include employment, the availability of good health services as well as the availability and reachability of leisure activities [29].

1.2.4 Interventions against social isolation and loneliness

The spectrum of interventions which are used to counteract the phenomenon of social isolation and to thereby prevent or combat its health consequences is diverse and complex. Typically, a 3-part categorization is employed: group-based, one-on-one, and by intervention type [43]. In a systematic integrative review, Gardiner 2018 offers an example categorization of interventions [44] whose effectiveness was evaluated with the aid of different empirical study designs.

These include:

Interventions aiming to promote participation in social life

This group often contains interventions intended to promote social interactions among affected people. These are primarily group programmes which may address special topics such as cultural traditions, passions and hobbies, or health-related topics. This group also includes interventions aiming to help participants maintain their social network in daycare facilities and through technology-based solutions such as video conferencing technology.

Psychological therapies aiming to change maladaptive patterns

This category includes therapeutic approaches and programmes conducted by professional therapists – e.g. in the form of humour therapy, mindfulness and stress reduction training, reminiscence group therapies, and interventions to provide cognitive and social support.

Interventions within health and social care

This category contains formalized interventions conducted by social system actors or various health professionals. It includes special professional networks which initiate measures against loneliness in the elderly. In this category, Gardiner 2018 places nursing schools' visiting programs for elderly, socially isolated persons as well as interventions to restructure senior facilities in order to improve social interaction.

Pet-supported interventions

This category typically includes programmes with dogs or cats in which the elderly are to develop mechanisms to manage loneliness by compensating for lack of social support and companionship via a relationship with a pet. This also includes services involving robotic dogs, robotic seals, and other electronic animals.

Programmes for establishing friendships

These interventions are defined as tools to facilitate social contacts with the goal of establishing new friendships. They are typically offered in a one-on-one setting by volunteers, either in-person, by phone, or as pen pals.

Hobby and leisure groups

The last category defined by Gardiner 2018 is composed of interventions focusing on leisure and (further) development of skills such as operating computers or gardening.

In addition, some systemic approaches focus primarily on improving infrastructure, e.g. public transport, or promoting volunteer work [12,45]. However, these approaches are typically not offered by service providers of the health or social welfare system.

In particular, there are indications of the interventions' context playing a decisive role in terms of their effectiveness. Additionally, interventions which are based on a theoretical foundation and offer social activities and/or support within a group format tend to be more promising [43,44,46]. However, many interventions are not designed to account for the complex, multidirectional relationship between loneliness, social isolation, morbidity, and mortality [47].

1.3 Health services situation

In Germany, it is currently rare for interventions to prevent and combat social isolation and loneliness to be offered within the medical services system through Statutory Health Insurance (SGB V) and are more commonly found in the social care system, which is based on Social Code Books IX and XII. However, the medical services system and health insurers have a duty to cover the pathological consequences of social isolation and loneliness. Furthermore, loneliness already represents a stand-alone reason to seek a primary care consultation [48].

Section 20 SGB V on primary prevention and health promotion includes an explicit mandate to focus on evident risk factors via public health measures [49] which promote social integration among other things. Therefore, it is possible to enhance the statutory health insurance funds' efforts if evidence-based methods exist for preventing and combating social isolation and loneliness. To prevent isolation, the promotion of social integration is increasingly becoming an element of outpatient as well as inpatient geriatric rehabilitation concepts [50]. But typically, it is merely a minor element whenever rehabilitation measures of some type are conducted in a group setting [51].

Currently, however, it is not always possible to strictly distinguish "medical and health-related interventions" from interventions offered by the social assistance system. Special "services" offered by health insurance funds are rare and have become available only recently. For example, AOK Baden-Württemberg is one of the only health insurers to offer a service which aims primarily at combating loneliness, among other things. In 2020, like-minded people were to meet at 14 *Gesundnah* (Healthy Nearby) festivals to motivate each other to pursue a healthy lifestyle and take advantage of local services in the fields of sports, exercise, nutrition, and relaxation [52]. Another example is *BKK Verkehrsbau Union*, which will start in September to offer a practical online training for seniors on how to use digital health applications as part of a newly entered cooperation with the association *Wege aus der Einsamkeit e.V.* (Ways out of Loneliness) [53]. The training itself is both an instrument for social integration and the instrument for teaching skills which are not directly related to loneliness and social isolation.

1.4 Concerns of those proposing the topic

A member of the public asked whether effective interventions are available to prevent and reduce existing social isolation. The person argued that the problem of social isolation in the elderly is growing and is associated with both physical and psychological impairment.

The *ThemenCheck Medizin* staff at IQWiG developed an HTA research question on the basis of this suggestion.

2 Research questions

The aims of this investigation are to

- assess the benefit of interventions intended to favourably influence outcomes relevant for the target group by (a) resolving or (b) preventing social isolation or loneliness in comparison with care provided without these interventions or with minimal interventions, each (1) in persons aged 65 years and older who meet an objective criterion of social isolation and who subjectively suffer from loneliness or (2) in persons aged 60 years and older who exhibit risk factors for social isolation and loneliness,
- assess the cost (intervention cost) of interventions aiming to favourably influence target-group-relevant outcomes by (a) resolving or (b) preventing social isolation or loneliness, each (1) in persons aged 65 years and older who meet an objective criterion of social isolation and who subjectively suffer from loneliness or (2) in persons aged 60 years and older who exhibit risk factors for social isolation and loneliness,
- assess the cost effectiveness of interventions aiming to favourably influence target-group-relevant outcomes by (a) resolving or (b) preventing social isolation or loneliness in comparison with care provided without these interventions or with minimal interventions, each (1) in persons aged 65 years and older who either meet an objective criterion of social isolation and who subjectively suffer from loneliness or (2) in persons aged 60 years and older who exhibit risk factors for social isolation and loneliness, and
- review ethical, social, legal, and organizational aspects associated with the medical interventions.

3 Methods

3.1 Methods – benefit assessment

The benefit assessment's target population is persons aged 60 years and older who exhibit risk factors for social isolation and loneliness and persons aged 65 years and older who meet an objective criterion of social isolation and who subjectively suffer from loneliness. The investigational interventions are those aiming to prevent or resolve social isolation and loneliness. Comparator interventions are care as usual (CAU) or CAU with minimal intervention.

The investigation examined the following target-group-relevant outcomes:

- Mortality
- Morbidity, such as
  - clinical outcomes, mental (e.g. depression)
  - clinical outcomes, somatic (e.g. complications of disease)
- Adverse events
- Health-related quality of life
- Health-related social functioning and social participation, e.g.
  - social relationships and support
  - loneliness
  - psychological resources (e.g. self-efficacy, coping).

Only RCTs were included in the benefit assessment. There were no restrictions regarding the study duration.

In parallel to the preparation of the HTA report protocol, a search for systematic reviews was conducted in the MEDLINE database (which includes the Cochrane Database of Systematic Reviews) and the HTA database as well as on the websites of the National Institute for Health and Care Excellence (NICE) and the Agency for Healthcare Research and Quality (AHRQ).

It was ascertained whether at least 1 high-quality, current systematic review existed whose information retrieval was a suitable basis for the assessment.

When such a high-quality, current, systematic review was available, in a 2nd step, a supplementary search was conducted for studies for the period not covered by the systematic review(s). Otherwise, the search for studies was carried out without time restriction.

A systematic literature search for RCTs was conducted in the databases MEDLINE, Embase, and Cochrane Central Register of Controlled Trials.

Furthermore, study registries were searched for suitable studies.

Relevant studies were selected by 2 persons independently from one another. Any discrepancies were resolved by discussion between them. Data were extracted into standardized tables. To assess the qualitative certainty of results, outcome-specific and study-level criteria for the risk of bias were assessed, and the risk of bias was rated as high or low in each case. Results are presented separately for research questions on prevention versus treatment. Within these categories, interventions are distinguished by whether they are implemented by volunteers or by professionals in the social and health services sector. The results of the individual studies are described, organized by outcomes.

For each outcome, a conclusion is drawn regarding the available evidence of (greater) benefit and (greater) harm, with 4 levels of certainty of conclusion: Relevance was derived by calculating effect strength according to Hedges' g, assuming that relevance is certain if the effect estimator and the corresponding confidence interval (CI) lies fully above the irrelevance threshold of .02 or below -0.2.

The data provided either proof (highest certainty), an indication (moderate certainty), a hint (weakest certainty), or none of these 3 situations applied. The latter was the case if no data were available or the data available did not allow any of the other 3 conclusions to be drawn. In this case, the conclusion "There is no hint of (greater) benefit or (greater) harm" was drawn.

3.2 Methods – health economic assessment

The health economic assessment took into account intervention costs and cost effectiveness.

Germany currently lacks reimbursability for investigational interventions which were identified in the benefit assessment and can be used to prevent or combat social isolation and loneliness. For calculating intervention costs, the average resource consumption for the investigational interventions of (a) services provided by volunteers and (b) professional services was used as determined in the studies identified by the search for the health economic assessment. To estimate the price range applicable in Germany for the needed resources, the German prices of the individual cost components were identified on the basis of the calculated quantities. If prices from prior years were found, they were inflation-adjusted to the year 2020 using the German Consumer Price Index (CPI). On this basis, the total costs of the interventions in Germany were estimated.

Costs for the comparator interventions were not surveyed because, in the present HTA, these were primarily "no intervention (CAU, waiting groups)" or at most minimal intervention

(e.g. brochure with contact addresses for counselling centres) and thus associated with minimal or no intervention costs.

To determine cost effectiveness, a systematic search in the form of a focused information retrieval for cost-effectiveness/efficacy analyses, cost-utility analyses, or cost-benefit analyses was conducted in MEDLINE, Embase, and the HTA database. For supplementary information, comparative health economic studies drawing conclusions on the cost of the investigational intervention and comparator intervention in the form of cost-cost analyses were included. The relevant publications were selected by 1 person, with a 2nd person doing quality assurance. Data extraction was conducted in standardized tables by 1 person, and quality assurance was conducted by a 2nd person. The health economic studies were assessed with regard to their reporting quality, and the study results were described. Additionally, the transferability of results on cost effectiveness to the German healthcare system was assessed.

3.3 Methods – ethical aspects

Ethical aspects can be derived from ethical principles [54]. Ethical aspects arise when (a) 1 or more principles of medical ethics are disregarded ("ethical risk") or (b) 2 or more principles are in conflict ("ethical challenge") [55].

An ethics framework for public health was used as a basis [56] and expanded to 7 ethical principles following a comparison with the questionnaire by Hofmann [57]:

- beneficence (benefit dimension)
- nonmaleficence (harm dimension)
- self-determination
- justice
- human dignity
- efficiency
- legitimacy

For identifying ethical aspects related to interventions combating social isolation and loneliness in the elderly, 2 scoping literature searches were conducted in PubMed, PhilPapers, and Wiso Sozialwissenschaften. The focus was on (a) interventions combating social isolation and loneliness (intervention-specific aspects) and (b) the phenomenon of social isolation with loneliness per se (disease-specific aspects). In addition, the transcripts of interviews with affected people and volunteers as well as theory-based reflection by the report authors (based on the above-mentioned principle approach) served to identify additional ethical aspects.

The identified ethical aspects formed the basis for formulating concrete assessment criteria for interventions tackling social isolation and loneliness in the elderly. Having been worded as questions, the criteria for the assessment were commented and validated by all report authors against the background of the respective domain-specific information.

Based on the developed test questions, the identified interventions tackling social isolation and loneliness in the elderly were ethically assessed in a stakeholder workshop. This workshop was attended by the persons involved in the report as well as 2 persons with practical experience in elder care, geriatric nursing, and social work. In the process, the importance for the context of care relevant in this report was estimated and an assessment conducted.

3.4 Methods – social, legal, and organizational aspects

Social, legal, and organizational arguments and aspects address the mutual interactions between an examination or treatment method and the social environment (e.g. resource distribution within a society, access to technologies, patient preferences, social norms, and values).

They are found in publications, monographs, project reports as well as laws and regulations or on stakeholder websites. The publication type, publication status, and study type in which they are found are irrelevant.

In the HTA report, arguments and aspects were taken into account if they included conclusions on social, legal, and/or organizational aspects of the technology to be investigated.

For the analysis of social, legal, and organizational aspects, scoping searches were conducted in the following information sources:

- MEDLINE via Pubmed
- Web of Science Core Collection
- Juris
- national and regional registries
- laws, regulations, or guidelines
- interest-based information sources, e.g. websites of stakeholders and charities

The scoping searches focused, in particular, on reviews which investigated the introduction of measures and examined qualitative aspects. One reviewer screened the information from all information sources found in the scoping searches for statements on social, legal and/or organizational arguments and aspects of the technology to be investigated.

Afterwards, the following documents were checked for potential social, legal, and/or organizational arguments and aspects:

- RCTs included in the benefit assessment
- qualitative studies which were conducted and cited within the process evaluation studies included in the benefit assessment
- studies included in the health economic assessment
- protocols for documenting the interviews with the surveyed affected people and volunteers
- protocol of the stakeholder workshop

The check of the documents for statements on social, legal, and/or organizational arguments and aspects of the technology to be investigated was conducted by 1 person. A 2nd person performed quality assurance of the result.

The information processing on social and organizational aspects is based on the comprehensive conceptual framework suggested by Mozygemba 2016 [58], which is presented in Section 6.2, Figure 1.

The information processing regarding legal aspects was conceptualized individually for this report and followed the original information provided in legal texts and commentaries (see Table 59 in Section A5.4.2 of the full report).

3.5 Patient interviews

For the generation of the report protocol and following the INTEGRATE-HTA approach, 2 persons affected by social isolation and loneliness were interviewed regarding their experiences with interventions tackling social isolation and loneliness. In addition, aspects relevant for the target group, relevant subgroups, and relevant ethical, social, legal, and organizational aspects were discussed. The interviews were conducted by phone following a guideline in January 2021, with each interview taking about 45 minutes. Recruitment was conducted through a senior citizens' consultation centre as well as a mobile nursing service.

In addition, a volunteer with several years of experience providing services for people affected by social isolation and loneliness was interviewed. This interview was likewise conducted in January 2021 and took 45 minutes. The interviews focused on the interviewees' experiences with interventions, their acceptance, perceived barriers, conducive factors, as well as wishes for future services.

In the context of a stakeholder workshop, we additionally invited 2 professionals from the social assistance system for discussing the results with regard to ethical, social, legal, and

organizational aspects. The stakeholder workshop was moderated by the project manager of the HTA report.

The stakeholder workshop and the interviews were recorded, transcribed, and summarized in condensed form.

4 Results: Benefit assessment

4.1 Results of the comprehensive information retrieval

The information retrieval identified 18 publications on a total of 14 RCTs as being relevant for the research question of the benefit assessment (Table 1).

Further, 2 planned and 2 ongoing studies were found as well as 13 studies of unclear status.

The search strategies for bibliographic databases and trial registries are found in the appendix. The last search was conducted on 11 February 2021.

In accordance with the 2 research questions of the report, the results were presented separately for the prevention studies (prevention of social isolation and loneliness) and treatment studies (resolution and reduction of social isolation and loneliness). The categorization into prevention versus treatment study was based on the description in the studies. Furthermore, interventions provided by professionals and those implemented by volunteer assistants (hereinafter: volunteers) were differentiated. The key differentiator is that the former group works for pay.

Table 1: Studies included for the benefit assessment

Studies	Publication(s)	Reference(s)
Prevention studies		
Services provided by volunteers		
Chan 2017	Chan et al. 2017	[59]
Hind 2014 / Mountain 2014	Hind et al. 2014	[60]
	Mountain et al. 2014	[61]
Services provided by professionals		
Ristolainen 2020	Ristolainen et al. 2020	[62]
Saito 2012	Saito et al. 2012	[63]
Shvedko 2020	Shvedko et al. 2020	[64]
Zhang 2019	Zhang et al. 2019	[65]
Treatment studies		
Services provided by volunteers		
Conwell 2020	Conwell et al. 2020	[66]
Fields 2020	Fields et al. 2020	[67]
Heller 1991	Heller et al. 1991	[68]
MacIntyre 1999	MacIntyre et al. 1999	[69]
Onrust 2008 / 2010	Onrust et al. 2008	[70]
	Onrust et al. 2010	[71]
Services provided by professionals		
Cohen-Mansfield 2018	Cohen-Mansfield et al. 2018	[72]

Studies	Publication(s)	Reference(s)
Pynnönen 2018	Pynnönen et al. 2018	[73]
Routasalo 2009 / Pitkala 2009 / 2011	Routasalo et al. 2009	[74]
	Pitkala et al. 2009	[75]
	Pitkala et al. 2011	[76]

Table 2: Study pool of the benefit assessment

Study	Available documents		
	Publications included	Full publication (in scientific journals)	Registry entry / result report from trial registries
Chan 2017	Chan et al. 2017	Yes	Yes [77]/no
Cohen-Mansfield 2018	Cohen-Mansfield et al. 2018	Yes	Yes [78]/no
Conwell 2020	Conwell et al. 2020	Yes	Yes [79]/no
Fields 2020	Fields et al. 2020	Yes	No/no
Heller 1991	Heller et al. 1991	Yes	No/no
Hind 2014 / Mountain 2014	Hind et al. 2014	Yes	No/yes (in the Appendix of Hind et al. 2014 [60])
	Mountain et al. 2014	Yes	
MacIntyre 1999	MacIntyre et al. 1999	Yes	No/no
Onrust 2008 / 2010	Onrust et al. 2008	Yes	No/no
	Onrust et al. 2010	Yes	
Pynnonen 2018	Pynnonen et al. 2018	Yes	No/no
Ristolainen 2020	Ristolainen et al. 2020	Yes	No/no
Routasalo 2009 / Pitkala 2009/ 2011	Routasalo et al. 2009	Yes	Yes [80]/no
	Pitkala et al. 2009	Yes	
	Pitkala et al. 2011	Yes	
Saito 2012	Saito et al. 2012	Yes	No/no
Shvedko 2020	Shvedko et al. 2020	Yes	Yes [81]/no
Zhang 2019	Zhang et al. 2019	Yes	Yes [82]/no

4.2 Characteristics of the studies included in the assessment

4.2.1 Characteristics of the prevention studies

Section 4.2.1.1 summarizes the included studies which primarily aim to prevent social isolation with loneliness in at-risk persons aged 60 years and older.

4.2.1.1 Study design and study population

Two studies investigated the effectiveness of interventions implemented by volunteers.

In a Japanese 6-month study enrolling a total of 48 participants, Chan 2017 compared the effectiveness of a combined programme consisting of a Tai Chi Qigong course and support by neighbourhood health ambassadors versus CAU. Goals were to strengthen social networks and promote psychological well-being. The Tai Chi Qigong course consisted of 2 one-hour training sessions per week for 3 months. Furthermore, participants were encouraged to independently practice the exercises daily for at least 30 minutes. They received accompanying support by trained laypersons who lived in the immediate vicinity, acted as health ambassadors, reminded intervention-group participants of the courses, and started self-directed practice groups where participants jointly practised their daily Tai Chi Qigong exercises in a park. The control group received CAU with sporadic home visits by social workers and regularly provided information about community services. Inclusion criteria were age 60 years and older as well as low to no involvement in social activities. The mean age of study participants was about 77 years.

A British pilot study with a total of 157 participants conducted by Hind 2014 / Mountain 2014 compared both the feasibility and the effectiveness of phone pal programmes in comparison with no intervention with regard to increasing health-related quality of life. The goal of the intervention was to initiate phone friendships between participants and to thereby enlarge their social network. For this purpose, the persons received a once-weekly, 10 to 20-minute phone call from the same volunteer in order to establish a personal connection. This initial phase was to be followed by weekly 1-hour telephone conferences with 6 intervention group participants each, led by the volunteer. The control group received the usual health and social care. To be included in the study, individuals had to be aged 75 years or older, have good cognitive functioning, and live in their private homes without support. The study participants' average age was about 80 years. The study was discontinued early because it was not possible to recruit enough volunteers within the specified period and hence not all included participants received the intervention.

Four studies investigated the effectiveness of interventions implemented by professionals (Ristolainen 2020, Saito 2012, Shvedko 2020, Zhang 2019).

A 6-month Finnish study enrolling a total of 392 participants (Ristolainen 2020) investigated the effectiveness of a participative group programme with the key elements of (a) social support, (b) consultation, and (c) activities with regard to health-related quality of life. The contents and design of the five 2-to-3-hour meetings were freely chosen by intervention-group participants, and the meetings were led and supported by the nursing managers and scientists. The control group was not offered any services. Where necessary, the local services offered through the social and health care system were available (CAU). Inclusion criteria were the following: living alone at a minimum age of 65 years with deficits in health and wellness

as well as having utilized health and social services at least twice within the past 6 months. Participants' mean age was about 77 years.

The Saito 2012 study investigated the effectiveness of an intervention for tackling social isolation conducted in a Tokyo suburb with a total of 63 participants with regard to social contacts and well-being. Participants had to have relocated from the inner city to suburban Tokyo within the prior 2 years. Four 2-hour sessions taking place at 2-week intervals involved an introduction to the intervention programme, focus-group discussions on the relocation experience, a needs assessment, and a guided tour of the community. Control-group participants had the option of receiving the intervention after the 6-month follow-up period (waiting group). Inclusion criteria were prior relocation, a minimum age of 65 years, and living alone in a private home. Participants' mean age was about 73 years.

In Great Britain, a randomized feasibility study evaluated a 12-week intervention with a total of 25 participants. The intervention, which aimed to alleviate loneliness and stabilize mental and physical health via participation in physical activities, consisted of weekly group walks taking up to 90 minutes as well as workshops for health education and on social interaction (Shvedko 2020). The walks were intended to slightly increase in intensity over time and were guided by a certified trainer who also monitored vital signs. The control group was allowed to start the intervention after completion of the 12-week observation period (waiting group). Inclusion criteria were a minimum age of 60 years, being physically fit but having engaged in less than 20 minutes of moderate exercise per week in the last month, and a risk of loneliness score of ≥ 6 out of 9 points on a loneliness scale. Participants' mean age was about 68 years.

A 7-month intervention study from China investigated the effectiveness of a group intervention based on mutual support for empty-nesters, i.e. persons whose adult children had left the joint household (Zhang 2019). The intervention aimed to promote social support and was implemented in 3 phases. The first 2 months involved individual conversations, home visits, and education about social support. In this phase, participants' needs were to be sounded out, trust established, and interest in social interaction awakened. Months 3 and 4 involved group meetings with 2 to 3 participants intended to increase awareness and the willingness to both receive and give support. This phase likewise included training on both giving and receiving social support. In the 3rd phase, participants met in groups of 7 to 9 persons to practice their skills for drawing social support from group interactions. This phase was likewise accompanied by tutorials on using social support. The control group received a follow-up examination and had the option of starting with the intervention after 5 months (waiting group). Inclusion criteria were a minimum age of 60 years, at least 1 year of residence in the community before study start, and the absence of cognitive problems or other mental disorders. Participants' mean age was about 88 years.

Tables 18 to 21 in Part A3.2.1 of the full report provide detailed information on the characteristics of the prevention studies (Table 18), inclusion and exclusion criteria (Table 19), the interventions (Table 20), and the characteristics of the included study population (Table 21).

4.2.2 Characteristics of the treatment studies

Section 4.2.2.1 summarizes the included studies which primarily aimed to resolve or reduce social isolation and loneliness in persons aged 65 years and older.

4.2.2.1 Study design and study population

Five studies (Conwell 2020, Fields 2020, Heller 1991, MacIntyre 1999, Onrust 2008/2010) investigated the effectiveness of interventions which were conducted mainly by volunteers.

In a 12-month intervention study with a total of 369 participants from the United States, Conwell 2020 investigated the effectiveness of The Senior Connection (TSC), an established visiting programme run by the U.S. Aging Services Network with regard to the outcomes of suicidality, anxiety, and depression. The visits were conducted by same-age volunteers. The intervention group had 4 contacts per month, either in person or by phone. The control group received no intervention. The study included community-dwelling adults aged 60 years and older who, in the prior 2 weeks, had felt lonely or burdensome to others. Participants' mean age was 71 years. Originally, the study was intended to run for 24 months, but due to difficulties in recruiting volunteers and expiry of funding, its duration was reduced to 12 months.

In a study conducted in the United States, Fields 2020 investigated the effectiveness of training on the use of tablet computers and the internet in a total of 83 participants. Relevant outcomes were social contacts, loneliness, and use of technology. The training was conducted by volunteers. The intervention had a duration of 8 weeks, with new topics being covered once weekly, e.g. a discussion of hardware, tablet computer setup, email address setup and use, and use of social networks. After the intervention, participants were allowed to continue using the tablet computer and stylus pen. The study used a wait-list design for control. Inclusion criteria were a minimum age of 60 years, fewer than 2 social visits per month, and need for training on the use of digital technologies. Participants' mean age was 75 years.

Another US study investigated the effectiveness of an intervention with phone pals in terms of social contacts, health, activity, and mood. The study was conducted with 291 women, had a duration of 30 weeks, and consisted of 3 phases (Heller 1991). The 1st phase involved trained interviewers contacting study participants by phone weekly. In phase 2, intervention-group participants were divided into 5 groups based on whether they would actively call other participants, receive calls from other participants, rejected phone contacts with other

participants, agreed to additional phone contacts with study staff, or discontinued contact to the study staff. In phase 3, no one was actively called any longer, but calls between participants were allowed. The control group received no intervention at any point during the study. The study enrolled only women whose annual household income was below a pre-defined limit. Further, thresholds were defined for social support and subjective loneliness. The mean age was 74 years.

A Canadian pilot study by MacIntyre 1999 investigated the effect of weekly visits by volunteers, The Volunteer Friendly Visitor Programme, on life satisfaction and social support. University students visited intervention-group participants once weekly for 3 hours. Participants were free to decide which activities they wanted to engage in during this time, e.g. taking walks, talking, reading aloud, or providing support with activities in the household. A total of 22 participants were included in this 6-week intervention. The control group continued to receive nursing care and support in housekeeping (CAU). Eligible for enrolment were elderly people who were living in their private homes and had no cognitive impairments. Participants' mean age was about 79 years.

A Dutch study investigated the effectiveness of a widow-to-widow programme regarding mental health and quality of life in a total of 216 participants (Onrust 2008 / 2010). The intervention group was visited by volunteers who were likewise widowed. The visits were intended to provide support via the exchange of experiences and sharing of emotions as well as through referral to self-help groups. The number of visits was determined as per participants' wishes (10 to 12 visits were assumed). The control group received CAU plus a brochure about depressive moods and signs of depression. Inclusion criteria were loss of a spouse/partner 6 to 9 months prior to study start, minimum age of 55 years, moderate to severe feeling of loneliness, and absence of mental disorders. Participants' mean age was about 69 years.

The effectiveness of professionally conducted interventions was investigated by 3 studies (Cohen-Mansfield 2018, Pynnönen 2018, Routasalo 2009 / Pitkala 2009 / 2011).

In Israel, the effectiveness of the 9-month I-SOCIAL (Increasing SOcial Competence and social Integration of older Adults experiencing Loneliness) project with regard to increasing social participation and reducing loneliness was investigated in a total of 89 participants (Cohen-Mansfield 2018). In up to 10 one-on-one meetings with a professional "activities counsellor", options for reducing barriers to social participation were developed. In up to 7 group meetings, the newly learned social skills were practised, and barriers and potential solutions were discussed with other affected people. The control group received no intervention. To be eligible, adults had to be at least 65 years old, feel lonely, have a score of >22 points in the Mini-Mental State Examination (MMSE), and have not been diagnosed with depression. Participants' mean age was about 78 years.

The intervention investigated by the Finnish study Pynnönen 2018 aimed to promote social contacts as well as to improve mental health. Participants were asked to select the activity they believed would be of most benefit to them: (a) sports/exercise in small groups, (b) social activities such as excursions, or (c) personal counselling. The study had a total duration of 18 months and enrolled a total of 257 participants. The control group received no intervention. Enrolled were persons aged 75 to 79 years old who felt lonely, melancholy, or had depressive moods and scored over 21 points on the MMSE scale. The mean age was about 77 years.

Another study from Finland investigated the effectiveness of psychosocial group rehabilitation with regard to loneliness, social activities, and mental well-being in a total of 235 participants (Routasalo 2009 / Pitkala 2009 / 2011). Weekly meetings with group leaders were held in various day clinics. Participants were free to choose the intervention group in which they wanted to participate: (a) therapeutic writing and psychotherapy, (b) sports/exercise and discussion of health-related topics, or (c) arts and stimulating activities (music, theatre, painting). The total observation period was 24 months. The control group received no intervention. Inclusion criteria were subjective loneliness and age 74 years or older. The mean participant age was 80 years.

Tables 23 to 26 in Part A3.2.2 of the full report provide detailed information on the characteristics of the treatment studies (Table 23), inclusion and exclusion criteria (Table 24), interventions (Table 25), and the characteristics of the included study population (Table 26).

4.3 Overview of target-group-relevant outcomes

4.3.1 Target-group-relevant outcomes from the prevention studies

Six prevention studies lent themselves to the extraction of data on patient-relevant outcomes. Table 3 presents an overview of the data available on patient-relevant outcomes from the included studies. None of the studies reported data on adverse events or mortality.

Table 3: Matrix of target-group-relevant outcomes – prevention studies

Outcomes	**Prevention studies**					
	Services provided by volunteers		**Services provided by professionals**			
	Chan 2017	**Hind 2014 / Mountain 2014**	**Ristolainen 2020**	**Saito 2012**	**Shvedko 2020**	**Zhang 2019**
Mortality	-	-	-	-	-	-
Morbidity						
Depression	-	●	-	●	●	-
Anxiety	-	-	-	-	●	-
Mental health	●	●[a]	-	-	-	-
Physical functioning	-	●	-	-	-	-
Physical role functioning	-	●	-	-	-	-
Bodily pain	-	●	-	-	-	-
Vitality	-	●	-	-	-	-
Health status	-	●[b]	-	-	-	-
Health-related quality of life						
SF-36 Physical Component Summary	-	●	-	-	-	-
SF-36 Mental Component Summary	-	●	-	-	-	-
EQ-5D Index	-	●	-	-	-	-
SF-12 Physical Component Summary	●	-	-	-	-	-
SF-12 Mental Component Summary	●	-	-	-	-	-
WHOQOL-Bref Index	-	-	●	-	-	-
Adverse events	-	-	-	-	-	-
Health-related social functioning and social participation						
Loneliness	●	●	●	●	●	-
Social participation:						
Social support	●	-	-	●	●	●
Social network	●	-	-	●	●	-
Social activities	-	-	-	●	-	-

Outcomes	Prevention studies					
	Services provided by volunteers		Services provided by professionals			
	Chan 2017	Hind 2014 / Mountain 2014	Ristolainen 2020	Saito 2012	Shvedko 2020	Zhang 2019
Satisfaction with social contacts	-	-	-	-	●	-
Trust in people	-	-	●	-	-	-
Institutional trust	-	-	●	-	-	-
Familiarity with services for the elderly	-	-	-	●	-	-
Psychological resources:						
Self-worth	●	-	-	-	-	-
Exercise self-efficacy	-	-	-	-	●	-
General self-efficacy expectations	-	●	-	-	-	-
Social functioning	-	●	-	-	-	-
Emotional role functioning	-	●	-	-	-	-
Well-being	-	●	-	-	-	-
Life satisfaction	-	-	-	●	-	-

● Data were reported and usable
- No data were reported (no further information) / Outcome was not surveyed

Notes:
a: The outcome is the study's primary outcome.
b: Outcome was surveyed twice with different instruments.

4.3.2 Target-group-relevant outcomes from the treatment studies

Eight treatment studies lent themselves to extracting data on patient-relevant outcomes. Table 4 presents an overview of the data available on patient-relevant outcomes from the included studies. One study reported data on the primary outcome "use of digital technology", but these data were irrelevant for the benefit assessment. None of the studies reported data on adverse events.

Table 4: Matrix of target-group-relevant outcomes – treatment studies

Outcomes	**Treatment studies**							
	Services provided by volunteers					**Services provided by professionals**		
	Conwell 2020	**Fields 2020**	**Heller 1991**	**MacIntyre 1999**	**Onrust 2008 / 2010**	**Cohen-Mansfield 2018**	**Pynnönen 2018**	**Routasalo 2009 / Pitkala 2009/ 2011**
Mortality	-	-	-	-	-	-	-	●
Morbidity								
Depression	●	-	●	-	●	-	●	-
Anxiety	●	-	-	-	●	-	-	-
Suicidality	●	-	-	-	-	-	-	-
Melancholy	-	-	-	-	-	-	●	-
Grief	-	-	-	-	●	-	-	-
Somatization	-	-	-	-	●	-	-	-
Health status	-	-	-	●	-	-	-	●
Cognitive performance	-	-	-	-	-	-	-	●
Adverse events	-	-	-	-	-	-	-	-
Health-related quality of life								
EQ-5D Index	-	-	-	-	●	-	-	-
15D Index	-	-	-	-	-	-	-	●
Health-related social functioning and social participation								
Loneliness	-	●	●	-	-	●[a]	●	●
Social participation:								
Social support	-	●	-	●	-	-	-	●
Support from family members	-	-	●	-	-	-	-	-
Support from friends	-	-	●	-	-	-	-	-
Social cohesion	-	-	-	-	-	-	●	-
Psychological strains:								
Life satisfaction	-	-	-	●	-	-	-	-
Well-being	-	-	●	-	-	-	-	●
Sense of belonging	●	-	-	-	-	-	-	-

Outcomes	Treatment studies							
	Services provided by volunteers					Services provided by professionals		
	Conwell 2020	Fields 2020	Heller 1991	MacIntyre 1999	Onrust 2008 / 2010	Cohen-Mansfield 2018	Pynnönen 2018	Routasalo 2009 / Pitkala 2009/ 2011
Perceived burdensomeness	●	-	-	-	-	-	-	-
Additional primary outcome								
Utilization of digital technology[b]	-	○	-	-	-	-	-	-

●: Data were reported and were usable.

○: Data were reported but irrelevant for the benefit assessment.

-: No data were reported (no further information) / The outcome was not surveyed

Notes:

a: The outcome is the study's primary outcome.

b: Outcome was reported by the authors as being one of the primary outcomes of the study. The utilization of digital technology was surveyed by asking participants whether they had recently used the Internet and how they would describe their skills in conducting internet searches and sending emails.

4.4 Assessment of the risk of bias of the results

4.4.1 Risk of bias of prevention studies

The risk of bias was rated as high on the study level for all 6 studies (Chan 2017 and Hind 2014 / Mountain 2014 [services provided by volunteers] Ristolainen 2020, Saito 2012, Shvedko 2020 and Zhang 2019 [services provided by professionals])

In the Chan 2017 and Hind 2014 / Mountain 2014 studies, neither patients nor treatment providers were blinded. For Chan 2017, a registration was found, but the outcomes differed between the registration and publication. Both studies reported an adequate randomization sequence and concealed group allocation.

In the Ristolainen 2020, Saito 2012, Shvedko 2020, and Zhang 2019 studies, neither participants nor treatment providers were blinded. In Ristolainen 2020 and Saito 2012, it remains unclear whether reporting bias can be ruled out because there was no evidence of study protocols or registry entries. It also remains unclear whether an adequate randomization sequence was used or whether group allocation was concealed. The Zhang 2019 study blinded neither patients nor treatment providers. Due to the registry entry and the publication exhibiting inconsistencies regarding outcomes, reporting bias cannot be ruled out.

In the Shvedko 2020 study, neither participants nor treatment providers were blinded. The randomization sequence was adequate, and group allocation was concealed. Shvedko 2020 was a pilot study.

The risk of bias at the outcome level was not determined for any of the 6 studies because the high risk at study level extends to the risk of bias at outcome level.

Table 22 in Appendix A3.2.2.5 of the full report presents the risk of bias across outcomes for the prevention studies.

4.4.2 Risk of bias in the treatment studies

The risk of bias was rated as high across outcomes for all 8 studies (Conwell 2020, Fields 2020, Heller 1991, MacIntyre 1999 and Onrust 2008 / 2010 [services provided by volunteers] Cohen-Mansfield 2018, Pynnönen 2018 and Routasalo 2009 / Pitkala 2009 / 2011 [services provided by professionals]).

Neither participants nor treatment providers were blinded in any of the studies. The documentation on the randomization sequence was unclear in Fields 2020, Heller 1991, and MacIntyre 1999. The randomization sequence was clearly documented in Conwell 2020 and Onrust 2008/2010. While it was unclear whether group allocation was concealed in

Fields 2020, Heller 1991, and MacIntyre 1999, this was clearly done in Conwell 2020 and Onrust 2008 / 2010. Due to missing information on study protocols or lack of effect estimators, reporting bias cannot be ruled out for Fields 2020, Heller 1991, MacIntyre 1999, or Onrust 2008 / 2010. The Conwell 2020 study was stopped before it was possible to record the primary outcome after 24 months.

For the Cohen-Mansfield 2018 study, it was unclear whether the randomization sequence was adequate or whether the group allocation was concealed. Furthermore, in the absence of any references to a study protocol, it was impossible to rule out reporting bias. Routasalo 2009/ Pitkala 2009 / 2011 reported an adequate randomization sequence and concealed group allocation. Reporting bias cannot be ruled out because there was no evidence of a study protocol. Pynnönen 2018 reported an adequate randomization sequence, but it remains unclear whether group allocation was concealed. For this study, reporting bias cannot be ruled out either as the study protocol was unavailable. In all studies investigating professionally performed interventions, neither patients nor treatment providers were blinded.

For all 8 studies, determining the risk of bias at outcome level was foregone because the high risk of bias at study level extends to the risk of bias at outcome level.

Table 27 in Appendix A3.2.2.5 of the full report presents the risk of bias across outcomes in the treatment studies.

4.5 Results on target-group-relevant outcomes

A detailed description of all employed survey instruments is found in the section HTA Details A3.3, Table 28 of the full report.

4.5.1 Results from the prevention studies

The following section presents the results on target-group-relevant outcomes which were surveyed in the prevention studies. For a better overview, a table first presents the intervention types investigated in each study (Table 5), and another table shows an overview of the study results on target-group-relevant outcomes (Table 6).

The prevention studies can be generally grouped into the following intervention types:

Table 5: Intervention types used in prevention studies

Study	Intervention type
Chan 2017	Tai Chi Qigong intervention in combination with volunteer health guides
Hind 2014 / Mountain 2014	Phone calls / phone pals with volunteers
Ristolainen 2020	Professional-led group services

Saito 2012	Professional-led group services
Shvedko 2020	Professional-led group services
Zhang 2019	Professional-led group services

To facilitate comparisons, Table 6 presents the survey times and intervention durations.

Table 6: Overview of effects with regard to target-group-relevant outcomes on the individual study level – prevention studies

Outcomes	**Prevention studies**					
	Services provided by volunteers		**Services provided by professionals**			
	Chan 2017	**Hind 2014 / Mountain 2014**	**Ristolainen 2020**	**Saito 2012**	**Shvedko 2020**	**Zhang 2019**
Survey time (months after baseline)	6	6	6	8	3	7
Duration of intervention (months)	3	4 ½	6	2	3	7
Follow-up duration (months)	3	1 ½	0	6	0	0
Morbidity						
Depression	-	↔	-	↔	↔	-
Anxiety	-	-	-	-	↔	-
Mental health	↔	↑	-	-	-	-
Physical functioning	-	↔	-	-	-	-
Physical role functioning	-	↑	-	-	-	-
Bodily pain	-	↑	-	-	-	-
Vitality	-	↔	-	-	-	-
General health status	-	↔	-	-	-	-
Health status	-	↔	-	-	-	-
Health-related quality of life						
SF-36 Physical Component Summary	-	↔	-	-	-	-
SF-36 Mental Component Summary	-	↔	-	-	-	-
EQ-5D Index	-	↔	-	-	-	-
SF-12 Physical Component Summary	↔	-	-	-	-	-

Outcomes	Prevention studies					
	Services provided by volunteers		Services provided by professionals			
	Chan 2017	Hind 2014 / Mountain 2014	Ristolainen 2020	Saito 2012	Shvedko 2020	Zhang 2019
Survey time (months after baseline)	6	6	6	8	3	7
Duration of intervention (months)	3	4 ½	6	2	3	7
Follow-up duration (months)	3	1 ½	0	6	0	0
SF-12 Mental Component Summary	↔	-	-	-	-	-
WHOQOL-Bref	-	-	↔	-	-	-
Health-related social functioning and social participation						
Loneliness	↑	↔	↔	↑	↔	-
Social participation:						
Social support	↗[a]	-	-	↑	↔	↑
Social network	↔	-	-	↔	↔	-
Social activities	-	-	-	↔	-	-
Satisfaction with social contacts	-	-	-	-	↔	-
Trust in people	-	-	↗[b]	-	-	-
Institutional trust	-	-	↗[c]	-	-	-
Familiarity with services for the elderly	-	-	-	↑	-	-
Psychological resources:						
Self-worth	↔	-	-	-	-	-
Exercise self-efficacy	-	-	-	-	↔	-
General self-efficacy expectations	-	↔	-	-	-	-
Social functioning	-	↑	-	-	-	-
Emotional role functioning	-	↔	-	-	-	-
Well-being	-	↔	-	-	-	-
Life satisfaction	-	-	-	↑	-	-

↑: Statistically significant effect in favour of the intervention

↗: Numerical difference in favour of the intervention without reported significance level OR individual items/subscales of the instrument exhibit a statistically significant effect in favour of the intervention

↔: No statistically significant difference

Outcomes	Prevention studies					
	Services provided by volunteers		Services provided by professionals			
	Chan 2017	Hind 2014 / Mountain 2014	Ristolainen 2020	Saito 2012	Shvedko 2020	Zhang 2019
Survey time (months after baseline)	6	6	6	8	3	7
Duration of intervention (months)	3	4 ½	6	2	3	7
Follow-up duration (months)	3	1 ½	0	6	0	0
-: No data reported						
Notes: a: For 1 of 2 items, the authors report a statistically significant effect in favour of the intervention. b: For 1 of 2 items, the authors report a statistically significant effect in favour of the intervention. c: For 1 of 6 items, the authors report a statistically significant effect in favour of the intervention.						

4.5.1.1 Morbidity parameters

Four of the 6 prevention studies reported morbidity parameters as outcomes. Effects on depression were recorded in a total of 3 studies. For measurement, Hind 2014 / Mountain 2014 used the Patient Health Questionnaire-9 item (PHQ-9), Saito 2012 used the Geriatric Depression Scale (GDS), and Shvedko 2020 the Hospital Anxiety and Depression Scale (HADS). Only 1 study (Shvedko) surveyed the outcome of anxiety using HADS. Chan 2017 used the Mental Health Inventory-18 Items (MHI-18) for surveying mental health. Hind 2014 / Mountain 2014 used the dimensions of the 36-item Short Form Health Survey (SF-36) for surveying mental health, physical functioning, physical role functioning, bodily pain, vitality, and general health status. Health status was additionally surveyed using the EuroQol 5-Dimension Utility Score (EQ-5D) visual analogue scale (VAS).

4.5.1.1.1 Depression and anxiety

Regarding the outcome of depression, Hind 2014 / Mountain 2014, Saito 2012, and Shvedko 2020 found no significant differences between intervention and control groups.

For the outcome of depression, this results in no hint of benefit, neither for services provided by volunteers in comparison with no intervention nor for services provided by professionals in comparison with waiting list.

Regarding the outcome of anxiety, Shvedko 2020 found no significant differences between the study groups.

For the outcome of anxiety, this results in no hint of benefit for services provided by professionals in comparison with a waiting group.

The detailed results are presented in Table 29: Results – depression and anxiety in Section A3.4.1 of the full report.

4.5.1.1.2 Mental health and somatization

Effects on mental health were surveyed in Chan 2017 and Hind 2014 / Mountain 2014. While Chan 2017 did not find any significant between-group differences after 3 months nor after 6 months, while Hind 2014 / Mountain 2014 found a difference of 9.5 points (95% CI: [4.5; 14.5]) in favour of the intervention group after 6 months. To check the relevance of the determined between-group difference, the effect strength was calculated using Hedges' g, which equalled 0.341 (95% CI: -0.188 – 0.87). However, the 95% CI of the standardized mean difference (Hedges' g) was in the irrelevance range of -0.2 to 0.2. It can therefore not be inferred that the effect is relevant.

For the outcome of mental health, this results in no hint of benefit of services provided by volunteers in comparison with CAU or no intervention.

The detailed results are presented in Table 36: Results – mental health and somatization in Section A3.4.8 of the full report.

4.5.1.1.3 Physical functioning

For the SF-36 dimension of physical functioning, Hind 2014 / Mountain 2014 found no numerical differences between the control and intervention groups.

For the outcome of physical functioning, this results in no hint of benefit of services provided by volunteers in comparison with no intervention.

The detailed results are presented in Table 33: Results – physical functioning in Section A3.4.5 of the full report.

4.5.1.1.4 Physical role functioning

For the SF-36 dimension of physical role functioning, Hind 2014 / Mountain 2014 reported a difference of 20.2 points (95% CI: [9.9; 30.6]) in favour of the intervention group after 6 months. The calculated effect strength (Hedges' g) was 0.654 (95% CI 0.115 – 1.193) The 95% CI of the standardized mean difference (Hedges' g) is within the irrelevance range of -0.2 to 0.2. The effect can therefore not be inferred to be relevant.

For the outcome of physical role functioning, this results in no hint of benefit of services provided by volunteers in comparison with no intervention.

The detailed results are presented in Table 34: Results – physical role functioning in Section A3.4.6 of the full report.

4.5.1.1.5 Bodily pain

For the SF-36 dimension of bodily pain, Hind 2014 / Mountain 2014 reported a difference of 16.6 points (95% CI: [8; 25.3]) in favour of the intervention group after 6 months. The calculated effect strength (Hedges' g) was 0.608 (95% CI 0.071 – 1.146). The 95% CI of the standardized mean difference (Hedges' g) is within the irrelevance range of -0.2 to 0.2. The effect can therefore not be inferred to be relevant.

For the outcome of bodily pain, this results in no hint of benefit of services provided by volunteers in comparison with no intervention.

The detailed results are presented in Table 35: Results – bodily pain in Section A3.4.7 of the full report.

4.5.1.1.6 Vitality

For the SF-36 dimension of vitality, Hind 2014 / Mountain 2014 found no numerical difference between the control group and the intervention group.

For the outcome of vitality, this results in no hint of benefit of services provided by volunteers in comparison with no intervention.

The detailed results are presented in Table 46: Results – vitality in Section A3.4.16 of the full report.

4.5.1.1.7 Health status

Hind 2014 / Mountain 2014 surveyed health status with both the SF-36 dimension of general health and the EQ-5D VAS. No numerical difference between the groups was found for either of them. Hence, neither instrument documented any advantages for the intervention group with regard to health status.

For the outcome of health status, this results in no hint of benefit of services provided by volunteers in comparison with no intervention.

The detailed results are presented in Table 39: Results – health status in Section A3.4.11 of the full report.

4.5.1.2 Parameters of health-related quality of life

Three of the 6 studies reported on the outcome of health-related quality of life. Chan 2017 used the 12-item Short Form Health Survey (SF-12) with the physical and mental component

summary scales. Hind 2014 / Mountain 2014 used the EQ-5D Index as well as the SF-36 physical and mental component summary scales. Ristolainen 2020 used the World Health Organization Quality of Life – Short Form (WHO-QoL-Bref) to measure health-related quality of life with the item for the overall assessment of quality of life and the four domains of physical health (DOM1), psychological health (DOM2), social relationships (DOM3), and environmental health (DOM4).

None of the studies showed any statistically significant or numerical differences.

For the outcome of health-related quality of life, this results in no hint of benefit for services provided by volunteers nor for services provided by professionals in comparison with CAU or no intervention.

The detailed results are presented in Table 31: Results – health-related quality of life in Section A3.4.3 of the full report.

4.5.1.3 Parameters of health-related social functioning and social participation

All 6 studies reported outcomes on health-related social functioning and social participation.

Five studies provide results on loneliness: Chan 2017 and Hind 2014 / Mountain 2014 measured with the De Jong Gieveld scale, Ristolainen 2020 with the University of California at Los Angeles Loneliness Scale-12 Items (UCLA-LS-12), Shvedko 2020 with the University of California at Los Angeles Loneliness Scale-8 Items (UCLA-LS-8), and Saito 2012 with the Ando-Osada-Kodama loneliness scale (AOK-LS).

Four studies reported social support as an outcome. Chan 2017 reported results from the Social Support Questionnaire – Short Form (SSQ-6), Saito 2012 used 4 individual items each on emotional and instrumental support, while Shvedko 2020 and Zhang 2019 used questionnaires without providing any further details on them. Three studies reported social support as an outcome. Chan 2017 and Shvedko 2020 used Lubben´s Social Network Scale-6 Items (LSNS-6), while Saito 2012 employed an individual item on the frequency of contacts. Furthermore, Saito 2012 reported on the outcomes of social activities and familiarity with services, Shvedko 2020 on satisfaction with social contacts, and Ristolainen 2020 on trust in persons and institutional trust, each of them using questionnaires which were not defined in further detail.

Self-esteem (Rosenberg-Self-Esteem scale) was reported as an outcome by Chan 2017, self-efficacy for exercise (Self-Efficacy for Exercise Scale [SEE]) by Shevdko 2020, and general self-efficacy (General Self-Efficacy Scale [GSE]) by Hind 2014 / Mountain 2014. Further, the SF-36 dimensions of social functioning and emotional role functioning were reported by Hind 2014 / Mountain 2014. Saito 2012 measured life satisfaction using the Japanese version

of the Life Satisfaction Index-A (LSI-A). Hind 2014 / Mountain 2014 surveyed well-being using a scale by the Office for National Statistics (ONS).

4.5.1.3.1 Loneliness

Statistically significant between-group differences in favour of the intervention group were found by Chan 2017 after 6 months: intervention group mean (standard deviation [SD]) 3.8 (2.1) at baseline, 1.9 (1.8); control group 3.2 (1.8) at baseline, 2.7 (1.6); p = 0.033. The calculated effect strength (Hedges' g) was -0.469 (95% CI -1.055 – 0.118). The 95% CI of the standardized mean difference (Hedges' g) is within the irrelevance range of -0.2 to 0.2. The effect can therefore not be inferred to be relevant.

Saito 2012 found the following statistically significant differences in favour of the intervention group after 8 months: intervention group mean (SD) 12.1 (2.7) at baseline, 11.1 (no data; ND) and control group 11.9 (2.6) at baseline, 12.3 (ND), p = 0.011. Due to missing information, formally checking the effect strength for the between-group difference by means of Hedges' g was impossible.

In the publications Hind 2014 / Mountain 2014, Ristolainen 2020, and Shvedko 2020, no statistically significant between-group differences were found.

For the outcome of loneliness, this results in no hint of benefit of services provided by volunteers nor for services provided by professionals in comparison with CAU, waiting list, or no intervention.

The detailed results are presented in Table 30: Results – loneliness in Section A3.4.2 of the full report.

4.5.1.3.2 Social participation

Social participation was surveyed with the following outcomes:

- Social support (Chan 2017: SSQ-6; Saito 2012: 4 items of emotional support, 4 items of instrumental support; Shvedko 2020: Medical Outcomes Study Social Support Survey [MOSSSS]; Zhang 2019: Social Support Rating Scale [SSRS])
- Social network (Chan 2017 and Shvedko 2020: LSNS-6; Saito 2012: 1 question on the frequency of social contacts)
- Social activities (Saito 2012: 1 question on the frequency of participation in group activities)
- Satisfaction with social contacts (Shvedko 2020: 1 question)

The SSQ-6 used by Chan 2017 for measuring social support distinguishes the dimensions of number of contact persons and satisfaction with social contacts. The change in the total number of social contact persons did not differ in a statistically significant manner after 6 months. With regard to satisfaction with social support, statistically significant between-group differences were found in favour of the intervention group. After 6 months, the mean (SD) had increased in the intervention group from 14.2 (5.7) to 18.0 (5.4), while it remained largely unchanged in the control group, at 16.1 (5.0) and 16.7 (4.9), p = 0.044. The check for relevance of the between-group difference resulted in a Hedges' g of 0.252 (95% CI -0.329 – 0.832) for satisfaction with social support. The 95% CI of the standardized mean difference (Hedges' g) is within the irrelevance range of -0.2 to 0.2. The effect can therefore not be inferred to be relevant.

After 8 months, Saito 2017 likewise found a statistically significant difference in favour of the intervention group. In the intervention group, the means for social support slightly increased from baseline to follow-up (7.2 to 7.8). In the control group, they decreased (6.7 to 5.9), p = 0.013 (with higher scores indicating more social support). Due to lack of information, formally checking effect strength for the between-group difference by means of Hedges' g was impossible.

In the SSRS used by Zhang 2019, higher scores likewise indicate more social support. The scale provides a result for social support overall as well as for the subdimensions of objective support, subjective support, and utilization of support in the intervention group. The change in baseline at follow-up after 7 months showed statistically significant between-group differences in favour of the intervention group for all dimensions (p < 0.001):

- Social support overall: intervention group: mean (SD) at baseline 37.32 (8,94), follow-up 41.01 (6.80); control group: mean (SD) at baseline 37.10 (7.92), follow-up 36.38 (7.72).
- Objective support: intervention group: mean (SD) at baseline 8.23 (3.56), follow-up 9.47 (2.79); control group: mean (SD) at baseline 8.08 (3.16), follow-up 7.97 (3.10).
- Subjective support: intervention group: mean (SD) at baseline 21.76 (5.27), follow-up 23.22 (4.19); control group: mean (SD) at baseline 21.63 (4.69), follow-up 21.19 (4.61).
- Utilization of social support: intervention group: mean (SD) at baseline 7.33 (2.24), follow-up 8.35 (2.03); control group: mean (SD) at baseline 7.39 (1.97), follow-up 7.23 (1.84).

The effect strength of the between-group difference was checked by means of Hedges' g: for social support overall 0.635 (95% CI 0.42 – 0.85), objective support 0.507 (95% CI 0.294 – 0.721), subjective support 0.46 (95% CI 0.247 – 0.672), benefit of the support 0.579 (95% CI 0.365 – 0.794). For the total score and all 3 subdimensions, the 95% CI of the standardized

mean difference (Hedges' g) is fully outside the irrelevance range of -0.2 to 0.2. This was interpreted to be a relevant effect.

Shvedko 2020 found no significant between-group differences for social support. For the outcomes of social network (Saito 2012, Chan 2017, Shvedko 2020), social activities (Saito 2012), and satisfaction with social contacts (Shvedko 2020), no statistically significant between-group differences were found.

Hence, for the outcome of social support, there is a hint of benefit of professional-led group programmes (Zhang 2019: one-on-one conversations and group meetings for social support as in social group work) in comparison with a waiting list. For all other interventions with regard to social support as well as all other outcomes on social participation, no hints of benefit of services provided by volunteers or by professionals were found in comparison with CAU, waiting list, or no intervention.

The detailed results are presented in Table 41: Results – social participation in Section A3.4.12 of the full report.

4.5.1.3.3 Trust in people and institutions

As a social participation outcome, Ristolainen 2020 investigated trust in or mistrust against other people as well as institutional trust (institutions overall, government and public authorities, public healthcare, public social care, courts, police, municipal decision-making) based on participant's agreement with individual statements. Higher scores indicated greater trust.

After 6 months, a minor effect regarding trust in other people was found in favour of the intervention group: intervention group mean (SD) at baseline 3.2 (1.0), follow-up 3.3 (0.9); control group mean (SD) at baseline 3.2 (1.0), follow-up 3.2 (1.0); p = 0.05. With regard to the surveyed institutional trust, a between-group differences in favour of the intervention group were found only for trust in the government and public authorities: intervention group mean (SD) at baseline 3.2 (1.1), follow-up 3.3 (1.0); control group mean (SD) at baseline 3.2 (1.2), follow-up 3.0 (1.2); p = 0.015. The effect strength (Hedges' g) is 0.105 (95% CI -0.107 – 0.317) for trust in other people. With regard to trust in the government and public authorities, the effect strength (Hedges' g) was 0.27 (95% CI 0.057 – 0.482). The 95% CI of the standardized mean differences (Hedges' g) were each in the irrelevance range of -0.2 to 0.2. Hence, the effects cannot be derived to be relevant.

For the outcome of trust in other people or institutional trust, there was no hint of benefit of services offered by professionals in comparison with no intervention.

The detailed results are presented in Table 44: Results – trust in people and institutions is found in Section A3.4.14 of the full report.

4.5.1.3.4 Familiarity with services for the elderly

Saito 2012 surveyed familiarity with services for the elderly using a list of 8 services. After 8 months, the mean had increased in both groups. In the intervention group, it rose from a mean (SD) 2.4 (2.4) at baseline to 6.0 (ND) in the follow-up examination. The increase was less pronounced in the control group, rising from 3.9 (2.7) to 4.2 (ND); p = 0.008. The difference between baseline and study end is 3.6 points for the intervention group and 0.3 points for the control group. However, these changes are to be interpreted with reservations because the baseline data are raw data, while the follow-up data are adjusted values. Due to missing information, it was impossible to formally check relevance based on the effect strength (Hedges' g).

For the outcome of familiarity with services for the elderly, this results in no hint of benefit of services provided by professionals in comparison with a waiting list.

The detailed results are presented in Table 45: Results – familiarity with services for the elderly in Section A3.4.15 of the full report.

4.5.1.3.5 Psychological resources

No statistically significant differences between intervention and control groups were found in the investigation of self-esteem (Rosenberg Self-Esteem Scale) by Chan 2017, the GSE by Hind 2014 / Mountain 2014, or SEE by Shvedko 2020. For the SF-36 dimension of emotional role functioning and well-being (ONS) , Hind 2014 / Mountain 2014 found no numerical differences.

For the SF-36 dimension of social functioning, Hind 2014 / Mountain 2014 reported a numerical difference of 18.1 points (95% CI: [7.9; 28.3]) in favour of the intervention group. The effect strength (Hedges' g) was 0.511 (95% CI -0.022 – 1.045). The 95% CI of the standardized mean difference (Hedges' g) is within the irrelevance range of -0.2 to 0.2. The effect can therefore not be inferred to be relevant.

Saito 2012 reported a statistically significant difference in favour of the intervention group with regard to life satisfaction (LSI-A) after 6 months: intervention group mean (SD) at baseline 20.9 (2.3), after 6 months 22.8 (ND); control group: mean (SD) at baseline 21.2 (4.4), after 6 months 21.4 (ND); p = 0.039. The difference between baseline and study end is 1.9 points in the intervention group and 0.2 points in the control group. Again, it must be noted that raw data were reported for baseline and adjusted data for follow-up. Due to missing data, it was impossible to calculate effect strength (Hedges' g) for the formal check of relevance.

This results in no hints of benefit for services provided by volunteers nor for services provided by professionals in comparison with CAU, waiting list, or no intervention for any of the outcomes on psychological resources.

The detailed results are presented in Table 38: Results – psychological resources in Section A3.4.10 of the full report.

4.5.2 Results from the treatment studies

The following section presents the results on target-group-relevant outcomes which were surveyed in the treatment studies. For a better overview, a table first presents the intervention types investigated in each study (Table 7), and another table shows an overview of the study results on target-group-relevant outcomes (Table 8).

The treatment studies can be generally allocated to the following intervention types:

Table 7: Allocation of interventions to treatment studies

Study	**Intervention type**
Conwell 2020	Home visits by volunteers
Fields 2020	Technology training by volunteers
Heller 1991	Phone calls / phone pals with volunteers
MacIntyre 1999	Home visits by volunteers
Onrust 2008 / 2010	Home visits by volunteers
Cohen-Mansfield 2018	Professional-led group services
Pynnönen 2018	Professional-led group services
Routasalo 2009 / Pitkala 2009/ 2011	Professional-led group services

To facilitate a comparison, Table 8 presents the measurement times and durations of the interventions.

Table 8: Overview of effects with regard to target-group-relevant outcomes on the individual study level – treatment studies

Outcomes	**Treatment studies**							
	Services provided by volunteers					**Services provided by professionals**		
	Conwell 2020	**Fields 2020**	**Heller 1991**	**MacIntyre 1999**	**Onrust 2008 / 2010**	**Cohen-Mansfield 2018**	**Pynnönen 2018**	**Routasalo 2009 / Pitkala 2009/ 2011**
Survey time points (in months after baseline)	12	2	7 ½	1 ½	12	9	6/18	3/6/12/24
Duration of intervention (months)	12	2	5	1 ½	Unclear[a]	6	6	3
Follow-up duration (months)	0	0	2 ½	0	Unclear	3	12	21
Mortality	-	-	-	-	-	-	-	↑ (24 mos.)
Morbidity								
Depression	↔	-	↔	-	↔	-	↔ (6 mos.)	-
Anxiety	↑	-	-	-	↔	-	-	-
Suicidality	↔	-	-	-	-	-	-	-
Melancholy	-	-	-	-	-	-	↔ (6/18 mos.)	-
Grief	-	-	-	-	↔	-	-	-
Somatization	-	-	-	-	↔	-	-	-
Self-reported health status	-	-	-	↔	-	-	-	↑ (12 mos.)
Cognitive performance	-	-	-	-	-	-	-	↑ (3 mos.)
Health-related quality of life								
EQ-5D Index	-	-	-	-	↔	-	-	-
15D Index	-	-	-	-	-	-	-	↑ (12 mos.)
Health-related social functioning and social participation								
Loneliness	-	↔	↔	-	-	↑	↔ (6/18 mos.)	↔ (6 mos.)
Social participation:								

Outcomes	**Treatment studies**							
	Services provided by volunteers					**Services provided by professionals**		
	Conwell 2020	**Fields 2020**	**Heller 1991**	**MacIntyre 1999**	**Onrust 2008 / 2010**	**Cohen-Mansfield 2018**	**Pynnönen 2018**	**Routasalo 2009 / Pitkala 2009/ 2011**
Survey time points (in months after baseline)	12	2	7 ½	1 ½	12	9	6/18	3/6/12/24
Duration of intervention (months)	12	2	5	1 ½	Unclear[a]	6	6	3
Follow-up duration (months)	0	0	2 ½	0	Unclear	3	12	21
Social support	-	↔	-	↔	-	-	-	↔ (6 mos.)
Support from family members	-	-	↔	-	-	-	-	-
Support from friends	-	-	↔	-	-	-	-	-
Social cohesion	-	-	-	-	-	-	↗[b] (6 mos.)	-
Psychological resources:								
Life satisfaction	-	-	-	↑	-	-	-	-
Well-being	-	-	↔	-	-	-	-	↑ (12 mos.)
Sense of belonging	↔	-	-	-	-	-	-	-
Perceived burdensomeness	↑	-	-	-	-	-	-	-

↑: Statistically significant effect in favour of the intervention

↗: Numerical difference in favour of the intervention without reported significance level OR individual items/subscales of the instrument exhibit a statistically significant effect in favour of the intervention

↔: No statistically significant difference

-: No data reported

Abbreviations:

mos.: months

Notes:

a: Intervention length was not predefined; the assumption was that about 10 to 12 home visits had to be conducted per participant, but the participant was visited for as long as the need existed; the range was 0 to 30, at a mean of 8.3 visits.

b: For 1 of 6 items, the authors report a statistically significant effect in favour of the intervention.

4.5.2.1 Mortality

Routasalo 2009 / Pitkala 2009 / 2011 showed a statistically significant higher survival rate (in %) after 24 months; intervention group 97% and control group 90%. The adjusted hazard ratio for mortality was 0.39 (95% CI [0.15; 0.98], p = 0.044).

For the outcome of mortality, this results in a hint of benefit of professional-led group programmes (Routasalo 2009 / Pitkala 2009 / 2011: weekly group meeting with different programmes such as arts or sports) in comparison with no intervention.

The detailed results are presented in Table 37: Results – mortality in Section A3.4.9 of the full report.

4.5.2.2 Morbidity parameters

Among the morbidity outcomes, depression is reported most frequently (in 4 of the 8 studies). To survey morbidity, Conwell 2020 used the PHQ-9, while Heller 1991 and Onrust 2008 / 2010 used the Center for Epidemiological Studies Depression Scale (CES-D), and Pynnönen 2018 employed the GDS. Anxiety was discussed in 2 studies; Conwell 2020 measured anxiety with the Generalized Anxiety Disorder-7 item (GAD-7), and Onrust 2008/2010 used the Symptom Checklist, Anxiety subscale (SCL90-Anxiety). One study each reported on suicidality (Conwell 2020, Geriatric Suicide Ideation Scale [GSIS]), melancholy (Pynnönen 2018, individual item on the frequency of melancholy mood), grief (Onrust 2008 / 2010, Inventory of Complicated Grief-Revised [ICG-R]), somatization (Onrust 2008 / 2010, Symptom Checklist, Subscale Somatization [SCL90-Somatization]), and cognitive performance (Routasalo 2009 / Pitkala 2009 / 2011, Alzheimer´s Disease Assessment Scale-Cognitive Subscale [ADAS-COG]). Two studies used self-reported health status as an outcome: MacIntyre 1999 (Health Perception Questionnaire [HPQ]) and Routasalo 2009 / Pitkala 2009 / 2011 (individual item to be assessed on a four-level scale).

4.5.2.2.1 Depression and anxiety

In the publications by Conwell 2020 (PHQ-9), Heller 1991 (CES-D), Onrust 2008 / 2010 (CES-D), and Pynnönen 2018 (GDS), no statistically significant differences between intervention and control groups were found for the outcome of depression.

For the outcome of depression, this results in no hint of benefit of services provided by volunteers nor for services provided by professionals in comparison with no intervention or CAU.

For the outcome of anxiety (GAD-7), in contrast, Conwell 2020 reported statistically significant differences: intervention group from 8.08 (1.02) to 6.56 (1.02) versus control group from 7.86 (1.04) to 7.58 (1.11); the difference in favour of the intervention group was 1.23 (0.55);

p = 0.03. The calculation of the effect strength (Hedges' g) resulted in a value of -0.956 (95% CI -1.215 – -0.697). The 95% CI of the standardized mean difference (Hedges' g) is fully outside the irrelevance range of -0.2 to 0.2. This was interpreted to be a relevant effect.

Regarding the outcome of anxiety, Onrust 2008 / 2010 (SCL90-Anxiety) found no significant difference between the study groups.

For the outcome of anxiety, this results in a hint of benefit of a programme involving volunteers visiting participants at their private homes (Conwell 2020: a volunteer-based peer companionship programme) in comparison with no intervention. For another volunteer-based programme, no hint of benefit was found regarding the outcome of anxiety when compared with CAU.

The detailed results are presented in Table 29: Results – depression and anxiety in Section A3.4.1 of the full report.

4.5.2.2.2 Suicidality, melancholy, and grief

Conwell 2020 determined suicidality using GSIS. The Pynnönen 2018 study surveyed melancholy using a self-designed question. Onrust 2008 / 2010 determined the outcome of grief using the ICG-R; statistically significant between-group differences were not found in any of the 3 studies.

This results in no hint of benefit for services provided by volunteers nor for services provided by professionals in comparison with CAU or no intervention.

Section 3.4.13 of the full report presents results in detail in Table 42: Results – suicidality, melancholy, and grief and Table 43: Results – suicidality, melancholy, and grief (dichotomous outcome).

4.5.2.2.3 Mental health and somatization

Onrust 2008 / 2010 surveyed somatization using the SCL90-Somatization. No statistically significant differences were found between the intervention and control groups.

For the outcome of somatization, this results in no hint of benefit of services provided by volunteers in comparison with CAU.

The detailed results are presented in Table 36: Results – mental health and somatization in Section A3.4.8 of the full report.

4.5.2.2.4 Self-reported health status

The MacIntyre 1999 study surveyed self-reported health status using 3 questions from the HPQ. The questions relate to general perception of health status, pain, and worries about one's own health. The results are reported as change from baseline after a 6-week intervention or control. No statistically significant differences were found between groups.

Routasalo 2009 / Pitkala 2009 / 2011 asked participants to subjectively rate their health status on a 4-level scale. Subjective health was dichotomized by combining the 2 lower and 2 upper categories (healthy and sick). After 12 months, the percentage of participants rating themselves as “healthy” had considerably increased in the intervention group, while it had decreased in the control group (graphic illustration only). The between-group difference was statistically significant (p = 0.007).

For the outcome of health status, this results in a hint of benefit of professional-led group programmes (Routasalo 2009 / Pitkala 2009 / 2011: weekly group meeting with different offers such as arts or sports) in comparison with no intervention. Regarding another programme provided by volunteers, no hint of benefit was found regarding the outcome of health status in comparison with CAU.

Section 3.4.13 of the full report presents the detailed results in Table 39: Results – health status and Table 40: Results – health status (dichotomous outcome).

4.5.2.2.5 Cognitive performance

Routasalo 2009 / Pitkala 2009 / 2011 surveyed cognitive performance using the ADAS-COG. Higher values indicate more pronounced cognitive impairment. Study participants were to choose 1 of 3 intervention groups (arts, exercise, or therapeutic writing) based on their preferences. Within the groups, they were then randomized and allocated to the active intervention or the control condition (CAU). Three months after baseline, all study groups (active intervention groups as well as controls) exhibited negative mean differences, i.e. all groups showed improvement, although improvement was more pronounced in the active intervention groups. A statistically significant difference in favour of the intervention group was found for the composite intervention group (mean difference of -2.6 [95% CI: -3.4 to -1.8]) in comparison with the composite control group (mean difference of -1.6 [95% CI: -2.2 – -1.0]) (p = 0.023). Due to missing data, it was impossible to calculate effect strength (Hedges’ g) for the formal check of relevance.

For the outcome of cognitive performance, there was no hint of benefit of services provided by professionals in comparison with no intervention.

Section A3.4.4 of the full report presents the results in detail in Table 32: Results – cognitive performance.

4.5.2.3 Parameters of health-related quality of life

Two of 8 studies reported outcomes on health-related quality of life. Onrust 2008 / 2010 used the EQ-5D Index, while Routasalo 2009 / Pitkala 2009 / 2011 employed the 15D questionnaire to survey health-related quality of life.

Onrust 2008 / 2010 used the EQ-5D questionnaire for surveying health-related quality of life. Based on an index value in the range of 0 to 1, with 1 indicating the best possible health status and 0 the worst possible health status, no statistically significant difference between the intervention and control groups was found 12 months after baseline.

Routasalo 2009 / Pitkala 2009 / 2011 used the 15D questionnaire. It likewise surveyed health-related quality of life using an index value between 0 and 1. As in the EQ-5D index value, 1 represents the best possible and 0 the worst possible health status. At 12 months after the intervention, a statistically significant between-group difference was found in favour of the intervention group. The mean change was 0.008 (95% CI: - 0.006 – 0.022) in the intervention group and -0.015 (95% CI: - 0.033 – 0.003), (p = 0.047) in the control group. Due to missing information, it was not possible to formally check the relevance based on Hedges' g. According to the developer of the 15D questionnaire, no clinically meaningful change ("much the same / no change") is assumed at mean changes of >-0.015 to <0.015.

For the outcome of health-related quality of life, this results in no hint of benefit of services provided by volunteers nor for services provided by professionals in comparison with CAU or no intervention.

Section A3.4.3 of the full report presents the detailed results in Table 31: Results – health-related quality of life.

4.5.2.4 Parameters of health-related social functioning and social participation

Among the outcomes on health-related social functioning and social participation, the outcome of loneliness is reported most frequently (5 out of 8 studies). Fields 2020 used the University of California at Los Angeles Loneliness Scale-3 Items (UCLA-LS-3), Cohen-Mansfield 2018 a score formed from the results of 3 measuring instruments (UCLA-LS-8, individual item on the frequency of loneliness and individual item on severity of loneliness), Routasalo 2009 / Pitkala 2009 / 2011 the University of California at Los Angeles Loneliness Scale-20 Items (UCLA LS-20), Heller 1991 the scale by Paloutzian and Ellison, and Pynnönen 2018 an individual item on the frequency of loneliness.

Three of 8 studies reported on the outcome of social support. Fields 2020 measured the outcome with the Interpersonal Support Evaluation List (ISEL), MacIntyre 1999 with the Personal Resource Questionnaire (PRQ85-Part II), and Routasalo 2009 / Pitkala 2009 / 2011 with the LSNS. One study each measured the outcomes of support from family members

(Heller 1991, Perceived Social Support Scale – Family Members [PSS-FA]), support from friends (Heller 1991, Perceived Social Support Scale – Friends [PSS-FR]), and social cohesion (Pynnönen 2018, Social Provisions Scale [SPS]).

For measuring life satisfaction, MacIntyre 1999 used the Life Satisfaction Index (LSIZ). Two of 8 studies reported on the outcome of well-being: Heller 1991 (Philadelphia Geriatric Center Morale Scale [PGC]) and Routasalo 2009 / Pitkala 2009 / 2011 (Psychological Well-being Score [PWS]). Conwell 2020 surveyed sense of belonging (Interpersonal Needs Questionnaire, Subscale-Belonging [INQ-Belonging]) and perceived burdensomeness (Interpersonal Needs Questionnaire, Subscale-Burden [INQ-Burden]).

4.5.2.4.1 Loneliness

Five studies measured the outcome of loneliness using different instruments: Fields 2020 (UCLA LS-3), Heller 1991 (4-level loneliness scale by Paloutzian und Ellison), Cohen-Mansfield 2018 (score formed from UCLA LS-8 + question about frequency of loneliness + question about severity of loneliness), Pynnönen 2018 (question about frequency of sense of loneliness) and Routasalo 2009 / Pitkala 2009 / 2011 (UCLA LS-20). Except for Cohen-Mansfield 2018, none of the studies showed any statistically significant differences between the respective intervention and control groups.

Nine months after baseline, Cohen-Mansfield 2018 demonstrated a statistically significant between-group difference in favour of the intervention, with lower values on the scale indicating a lower level of loneliness: intervention group mean (SD) 3.05 (0.74) at baseline, 2.72 (0.67) after 9 months; control group mean (SD) 2.92 (1.05) at baseline, 2.92 (0.88) after 9 months; $p < 0,05$. The effect strength (Hedges' g) was calculated as -0.26 (95% CI of -0.759 – 0.239). The 95% CI of the standardized mean difference (Hedges' g) is within the irrelevance range of -0.2 to 0.2. The effect can therefore not be inferred to be relevant.

For the outcome of loneliness, this results in no hint of benefit of services provided by volunteers nor for services provided by professionals in comparison with waiting list or no intervention.

The detailed results are presented in Table 30: Results – loneliness in Section A3.4.2 of the full report.

4.5.2.4.2 Social participation

The following outcomes were selected for measuring social participation:

- social support (Fields 2020: ISEL, McIntyre 1999: PRQ85-Part II, Routasalo 2009 / Pitkala 2009 / 2011: LSNS)

- support from family members or friends (Heller 1991: PSS-FA, PSS-FR)
- social cohesion (Pynnönen 2018: SPS)

The Social Provisions Scale used by Pynnönen 2018 distinguishes 6 subscales: social integration, reliable alliance, guidance, attachment, opportunity for nurturance, and reassurance of worth. For the subscale of social integration, both examined groups exhibited higher values at 6 months after baseline compared to baseline, but this difference was more pronounced in the intervention group: intervention group: mean (SD) 12.30 (2.17) at baseline, 12.92 (2.0) after 6 months; control group: mean (SD) 12.75 (2.15) at baseline, 12.77 (2.18) after 6 months; p = 0.041. The effect strength (Hedges' g) was 0.072 (95% CI -0.192 – 0.335). The 95% CI of the standardized mean difference (Hedges' g) is within the irrelevance range of -0.2 to 0.2. The effect can therefore not be inferred to be relevant. No statistically significant between-group differences were found in the other subscales.

MacIntyre 1999 describes statistically significant between-group differences in 2 of 5 subdimensions of PRQ85-Part II. However, the developers of the instrument did not provide for an isolated presentation of the individual subdimensions; therefore, the outcome of social support is deemed not statistically significant.

The remaining studies did not report any statistically significant differences.

This results in no hint of benefit of services provided by volunteers nor for services provided by professionals in comparison with CAU, waiting list, or no intervention for any of the outcomes on social participation.

The detailed results are presented in Table 41: Results – social participation in Section A3.4.12 of the full report.

4.5.2.4.3 Psychological resources

MacIntyre 1999 surveyed life satisfaction using the LSIZ, with higher values indicating higher life satisfaction. After 6 weeks, the mean change (SD) was 2.83 (1.7) (baseline 11.9) in the intervention group and -3.3 (5.6) (baseline 12.2) in the control group. These between-group differences were statistically significant ($p < 0.01$) in favour of the intervention group. The effect strength (Hedges' g) was 1.471 (95% CI 0.526 – 2.416). The 95% CI of the standardized mean difference (Hedges' g) is fully outside the irrelevance range of -0.2 to 0.2. This was interpreted to be a relevant effect.

Heller 1991 investigated subjective well-being 7.5 months after baseline using the PGC, with higher scores reflecting higher subjective well-being; no statistically significant between-group differences were found. Routasalo 2009 / Pitkala 2009 / 2011 surveyed well-being using the PWS, with 1 being the best possible and 0 the worst possible well-being. The mean

change from baseline to 12 months was 0.11 (95% CI: 0.04 – 0.13) in the intervention group and 0.01 (95% CI: -0.05 – 0.07) in the control group. The between-group difference was statistically significant; p = 0.045. Due to missing data, it was impossible to calculate effect strength (Hedges' g) for the formal check of relevance.

Conwell 2020 used the INQ to survey sense of belonging (INQ-Belonging) and perception of burdensomeness (INQ-Burden). Six months after baseline, a statistically significant effect in favour of the intervention group was found only for INQ-Burden: intervention group mean (SE) 1.65 (0.41) at baseline, 1.19 (0.41) after 6 months; control group mean (SE) 1.43 (0.42) at baseline, 1.34 (0.42) after 6 months; p < 0.01. Higher values suggest more distress in the interpersonal domain. The check of relevance resulted in a Hedges' g of -0.361 (95% CI -0.609 to -0.114). The 95% CI of the standardized mean difference (Hedges' g) is within the irrelevance range of -0.2 to 0.2. The effect can therefore not be inferred to be relevant.

For the outcome of life satisfaction, this results in a hint of benefit of a home visit programme by volunteers (McIntyre 1999: a nursing service-developed programme involving weekly visits by volunteers) in comparison with CAU.

For all other outcomes on psychological resources, this results in no hints of benefit of services provided by volunteers nor for services provided by professionals in comparison with no intervention.

The detailed results are presented in Table 38: Results – psychological resources in Section A3.4.10 of the full report.

4.6 Evidence map

As described under 4.1, this HTA investigates studies pursuing 2 different goals (prevention and treatment studies) in which interventions are offered by 2 different groups of service providers (volunteers and professionals). Due to the complexity and differences between the employed interventions, it was impossible to combine them into composite groups in a generally meaningful way, e.g. via metaanalyses, in the presentation of the available evidence at the outcome level. The statistical heterogeneity of the results was therefore not checked.

Generally, proof of benefit of an intervention can be derived only if at least 2 studies with high qualitative certainty of results are available. An indication can be derived in case of the availability of (a) 1 study of high qualitative certainty of results or (b) 2 or more studies with moderate qualitative certainty of results and homogeneous results or results markedly pointing in the same direction or (c) 2 or more studies of high certainty of results and effects moderately pointing in the same direction. Hints can be derived from the results of (a) 1 study of moderate certainty of results, (b) several studies of low qualitative certainty of results and

effects markedly pointing in the same direction or (c) several studies of moderate certainty of results and effects moderately pointing in the same direction.

In the case of the present HTA, 14 RCTs with high risk of bias were included, i.e. the certainty of results was to be classified as moderate throughout. Therefore, it is impossible to derive any proof. Furthermore, no indications can be derived because effects pointing in the same direction from at least 2 studies were not available for any of the investigated outcomes.

For the prevention studies, it was possible to derive hints based on 1 study with moderate certainty of results for 1 outcome and 1 type of intervention:

Table 9: Hints derived from preventive studies

Outcome	Intervention	Study
Social support, surveyed with the Social Support Rating Scale (SSRS)	Services provided by professionals: "Self-mutual-group-based intervention", 7-month intervention in the form of social group work with the goal of enabling participants to independently establish and maintain contacts in order to build a social support network.	Zhang 2019

For the treatment studies, it was possible to derive hints, each based on 1 RCT of moderate certainty of results, for the following outcomes and intervention types:

Table 10: Hints derived from treatment studies

Outcome	Intervention	Study
Mortality Survival after 24 months	Services provided by professionals "Psychosocial group rehabilitation" is an intervention consisting of weekly group meetings for strengthening the self-determination of elderly people with the goal of promoting social integration and peer support.	Routasalo 2009 / Pitkala 2009 / 2011
Anxiety, surveyed with the Generalized Anxiety Disorder-7 item (GAD-7)	Services provided by volunteers: "The Senior Connection" is a standardized, volunteer-based peer companionship programme for older adults.	Conwell 2020
Self-reported health status Dichotomization of the results of a 4-part answer scale into "healthy" and "sick"	Services provided by professionals "Psychosocial group rehabilitation" is an intervention consisting of weekly group meetings for strengthening the self-determination of elderly people with the goal of promoting social integration and peer support.	Routasalo 2009 / Pitkala 2009 / 2011
Life satisfaction, surveyed with the	Services provided by volunteers:	MacIntyre 1999

Life Satisfaction Index Z (LSI-Z)	"The Volunteer Friendly Visitor Programme" was developed as a service to supplement care measures and help with housekeeping by mobile nursing services.	

Table 11 and Table 12 below show the evidence maps regarding target-group-relevant outcomes for the prevention and therapy studies.

Table 11: Evidence map regarding target-group-relevant outcomes from the prevention studies

Prevention studies						
	Services provided by volunteers		**Services provided by professionals**			
Outcomes	**Chan 2017**	**Hind 2014 / Mountain 2014**	**Ristolainen 2020**	**Saito 2012**	**Shvedko 2020**	**Zhang 2019**
Morbidity						
Depression	-	⇔	-	⇔	⇔	-
Anxiety	-	-	-	-	⇔	-
Mental health	⇔	⇔	-	-	-	-
Health status	-	⇔	-	-	-	-
Physical functioning	-	⇔	-	-	-	-
Physical role functioning	-	⇔	-	-	-	-
Bodily pain	-	⇔	-	-	-	-
Vitality	-	⇔	-	-	-	-
Health-related quality of life						
SF-36 Physical Component Summary	-	⇔	-	-	-	-
SF-36 Mental Component Summary	-	⇔	-	-	-	-
EQ-5D Index	-	⇔	-	-	-	-
SF-12 Physical Component Summary	⇔	-	-	-	-	-
SF-12 Mental Component Summary	⇔	-	-	-	-	-
WHOQOL	-	-	⇔	-	-	-
Health-related social functioning and social participation						
Loneliness	⇔	⇔	⇔	⇔	⇔	-
Social support	⇔	-	-	⇔	⇔	⇗
Social network	⇔	-	-	⇔	⇔	-
Social activities	-	-	-	⇔	-	-
Satisfaction with social contacts	-	-	-	-	⇔	-
Trust in people	-	-	⇔	-	-	-

Prevention studies						
	Services provided by volunteers		Services provided by professionals			
Outcomes	**Chan 2017**	**Hind 2014 / Mountain 2014**	**Ristolainen 2020**	**Saito 2012**	**Shvedko 2020**	**Zhang 2019**
Institutional trust	-	-	⇔	-	-	-
Familiarity with services for the elderly	-	-	-	⇔	-	-
Self-worth	⇔	-	-	-	-	-
Exercise self-efficacy	-	-	-	-	⇔	-
General self-efficacy expectations	-	⇔	-	-	-	-
Social functioning	-	⇔	-	-	-	-
Emotional role functioning	-	⇔	-	-	-	-
Well-being	-	⇔	-	-	-	-
Life satisfaction	-	-	-	⇔	-	-

⇗: Hint of (greater) benefit or hint of lesser harm
⇔: No hint, indication, or proof; homogeneous result
-: No data reported

Table 12: Evidence map regarding target-group-relevant outcomes from the treatment studies

	Treatment studies							
	Services provided by volunteers					Services provided by professionals		
Outcomes	**Conwell 2020**	**Fields 2020**	**Heller 1991**	**MacIntyre 1999**	**Onrust 2008 / 2010**	**Cohen-Mansfield 2018**	**Pynnönen 2018**	**Routasalo 2009 / Pitkala 2009/ 2011**
Mortality	-	-	-	-	-	-	-	⇗
Morbidity								
Depression	⇔	-	⇔	-	⇔	-	⇔	-
Anxiety	⇗	-	-	-	⇔	-	-	-
Suicidality	⇔	-	-	-	-	-	-	-
Melancholy	-	-	-	-	-	-	⇔	-
Grief	-	-	-	-	⇔	-	-	-
Somatization	-	-	-	-	⇔	-	-	-
Health status	-	-	-	⇔	-	-	-	⇗
Cognitive performance	-	-	-	-	-	-	-	⇔
Health-related quality of life								
EQ-5D Index	-	-	-	-	⇔	-	-	-
15D Index	-	-	-	-	-	-	-	⇔
Health-related social functioning and social participation								
Loneliness	-	⇔	⇔	-	-	⇔	⇔	⇔
Social support	-	⇔	-	⇔	-	-	-	⇔
Support from family and/or friends	-	-	⇔	-	-	-	-	-
Social cohesion	-	-	-	-	-	-	⇔	-
Life satisfaction	-	-	-	⇗	-	-	-	-
Well-being	-	-	⇔	-	-	-	-	⇔
Sense of belonging	⇔	-	-	-	-	-	-	-
Perceived burdensomeness	⇔	-	-	-	-	-	-	-

⇗: hint of (greater) benefit or hint of lesser harm
⇔: no hint, indication, or proof; homogeneous result
-: No data reported

5 Results: Health economic assessment

5.1 Intervention costs

In Germany, interventions for preventing and tackling social isolation and loneliness are currently not among the standard benefits paid for by the statutory health insurance. Therefore, the analysis of intervention costs is based on measures taken to tackle social isolation and loneliness which were identified in the context of the benefit assessment as interventions offered by different service providers and were shown in RCTs to be at least partially effective. These interventions are provided by volunteers or professionals. Health economic analyses were identified for 1 example of each of these interventions, and the presentation of intervention costs is based on these examples.

The expected cost of the widow-to-widow programme (Onrust 2008/2010) as an example of an intervention provided by volunteers equals on average about €403 or €246 per participant, depending on whether 1 or 3 volunteers participate in the coordinator's weekly supervision sessions. This estimated total price was calculated based on the quantity structure described by Onrust 2008/2010 and covers the organization and conduct of 10 to 12 home visits per participant. It includes the flat-rate costs for the coordinators' remunerations as well as volunteer time, costs for supervision, and costs of phone calls.

Since no information was available regarding the time needed for training or the preparation and conduct of home visits and subsequent supervisions, these costs were estimated. For the widow-to-widow programme, this results in one-time training costs before the start of the intervention equalling €2581 per coordinator and €1678 per volunteer.

For the Psychosocial Group Rehabilitation (Routasalo 2009 / Pitkala 2009 / 2011) as an example of a service provided by professionals, the total average cost for the 3-month group programme not taking into account the pre-intervention training cost for group leaders equals €434 per participant. The included services were estimated on the basis of the Routasalo 2009 / Pitkala 2009 / 2011 study and comprised the costs for the individual group programmes, transport costs, costs for beverages and meals during group meetings as well as the training and reimbursement of group leaders. The estimated average cost is based on weekly group meetings taking about 5 to 6 hours each over a 3-month period and is calculated per participant, as defined by Routasalo 2009 / Pitkala 2009 / 2011.

For this intervention, it is further worth noting that the pre-intervention training costs must be invested once at the start of the intervention; they equal €4195 for 1 group or €12 585 for 3 groups.

5.2 Systematic review of health economic evaluations

5.2.1 Results of the information retrieval

In the information retrieval, 2 studies were found to be relevant on the basis of the inclusion criteria and were included in the assessment. They were the Onrust 2008/2010 and Routasalo 2009 / Pitkala 2009 / 2011 studies. The searches did not find any other or ongoing health economic studies which meet the inclusion criteria.

The search strategies for bibliographic databases are found in the appendix. The last search was conducted on 8 February 2021.

Table 13: Study pool of the health economic assessment

Study	Documents relevant for the health economic evaluation [citation]
Onrust 2008 / 2010	Onrust, S.; Smit, F.; Willemse, G.; van den Bout, J.; Cuijpers, P. Cost-utility of a visiting service for older widowed individuals: randomised trial. BMC Health Services Research 2008; 8: 128. [70]
Routasalo 2009 / Pitkala 2009 / 2011	Pitkala, K. H.; Routasalo, P.; Kautiainen, H.; Tilvis, R. S. Effects of psychosocial group rehabilitation on health, use of health care services, and mortality of older persons suffering from loneliness: A randomized, controlled trial. Journals of Gerontology - Series A Biological Sciences and Medical Sciences 2009; 64(7): 792-800. [75]

5.2.2 Characteristics of the studies included in the assessment

For assessing cost effectiveness, the Dutch Onrust 2008 / 2010 study conducted a cost-utility analysis (CUA). Since no further cost-effectiveness/efficacy, cost-utility, or cost-benefit analyses were found, the cost-cost analysis by Routasalo 2009 / Pitkala 2009 / 2011 was included as supplementary information. This study did not provide any explicit information on study design. Based on the methodological approach, a cost-cost analysis was presumed to have been conducted.

Both of the health economic analyses are based on randomized controlled interventional studies which were also included in the benefit assessment part of the present HTA report. The Onrust 2008 / 2010 health economic study compared a visiting service with the sending of a brochure. Intervention-group participants were offered 10 to 12 home visits organized by trained coordinators and conducted by volunteers. Routasalo 2009 / Pitkala 2009 / 2011 compared professional-led group meetings on the topics of “arts and stimulating activities”, “sports and exercise and health-related discussions”, and “therapeutic writing” with the services offered in CAU. The offered group meetings took place weekly for 3 months, for 5 to 6 hours each.

Onrust 2008 / 2010 included a total of 216 persons in their investigation. Routasalo 2009 / Pitkala 2009 / 2011 is based on a total of 235 participants.

The primary outcome in Onrust 2008/2010 was health-related quality of life, which was measured via EQ-5D. The intervention group had a score of 0.76 (SD = 0.25) at baseline and a score of 0.80 (SD = 0.18) in the follow-up after 12 months. This result shows a significant improvement in the health-related quality of life of intervention-group participants. In the control group, in contrast, the effect was not found. It showed a score of 0.83 (SD = 0.18) at baseline and a score of 0.81 (SD = 0.21) at follow-up. In the inter-group comparison, no statistically significant difference was found with regard to quality of life.

Routasalo 2009 / Pitkala 2009 / 2011 investigated the survival rate 24 months after the intervention, both in the intervention group and in the control group. The survival rate in the intervention group was higher, at 97% (95% CI: [91%; 99%]), while that of the control group was 90% (95% CI: [83%; 95%]). Compared to the control group, the hazard ratio for mortality in the intervention group was 0.39 (95% CI: [0.15; 0.98]); p = 0.044.

In both studies, costs were reported in the currency EURO. Both studies determined prices using a base year in the early 2000s: 2003 (Onrust 2008 / 2010) and 2001 (Routasalo 2009 / Pitkala 2009 / 2011). Information on perspective is provided only by the authors of Onrust 2008 / 2010, who take a societal perspective, while Routasalo 2009 / Pitkala 2009 / 2011 provides no information on this topic.

Both studies recorded direct medical costs, with Onrust 2008/2010 surveying resource use with elements from the Medical Technology Assessment Questionnaire on Costs Associated with Psychiatric Illness (TiC-P) and contacts to facilities for mental illness in great detail. Routasalo 2009 / Pitkala 2009 / 2011, in contrast, reported only the costs of hospital and physician contacts under direct medical costs. Onrust 2008/2010 additionally reported non-medical costs such as patients' travel to the facilities.

Both studies calculated the intervention costs of the investigated measures. Onrust 2008 /2010 took into account training costs, coordinator reimbursements as well as time costs for volunteers and participants, costs incurred by the coordinators in the preparation of home visits, costs for subsequent supervision, and material costs for telephone calls made by the visiting service. In this case, the intervention costs are reported by the authors at €553 per person; the currency-converted and inflation-adjusted intervention costs equal €574 [83,84] per person.

For intervention costs, Routasalo 2009 / Pitkala 2009 / 2011 took into account the components of programme costs, transport costs, costs for meals, and the training and compensation of group leaders. Intervention costs were €881 per person, or a currency-converted and inflation-adjusted €1053 per person [83,84]

5.2.3 Results of health economic evaluations

Both publications reported the intervention costs incurred as part of the study. For volunteer visits, Onrust 2008/2010 determined average per-person intervention costs of €553, or a currency-converted and inflation-adjusted amount of €574 [83,84]. For the group programmes, Routasalo 2009 / Pitkala 2009 / 2011 calculate intervention costs of €881 per person, or a currency-converted and inflation-adjusted amount of €1053 [83,84].

In the comparison of intervention versus control group, the Dutch study (Onrust 2008/2010) shows a statistically non-significant cost difference of €210 ($p = 0.563$) per person, or a currency-converted and inflation-adjusted amount of €218 per person [83,84]. The difference in benefit between the intervention and control groups is likewise not statistically significant. Nevertheless, Onrust 2008/2010 determined the incremental cost-benefit ratio per patient to be €6827 per gained quality-adjusted life year (QALY) or a currency-converted and inflation-adjusted amount of €7085 per person [83,84]. In addition, the acceptance of the intervention was reported as a probability of 31% at a public willingness to pay (WTP) of zero, 55% at a WTP of €10,000, and 70% at a WTP of €20,000. Despite the cost and benefit difference not being statistically significant, the authors additionally calculated a positive incremental net monetary benefit (NMB) of €410 at a WTP of €20,000 and €2270 at a WTP of €80,000.

In the Finnish study, Routasalo 2009 / Pitkala 2009 / 2011 calculated a statistically significant cost difference of €-943 per person and year (95% CI: [-1955; -127]; $p = 0.039$) in favour of the intervention group, at a currency-converted and inflation-adjusted amount of €-1127 per person. This exceeds the reported intervention costs of €881 per person or a currency-converted and inflation-adjusted amount of €1053 [83,84].

With regard to clinical benefit, Routasalo 2009 / Pitkala 2009 / 2011 showed a statistically significant difference in mortality (hazard ratio of 0.039) in favour of the intervention group (95% CI: [0.15; 0.98]; $p = 0.044$) as well as a statistically significant improvement in subjective health ($p = 0.007$) in favour of the intervention group. No cost-outcome ratio was presented.

Reporting and methodological quality

Both studies describe the therapeutic indication, interventions for tackling social isolation and loneliness as well as the objective of the analysis. Regarding the presentation of methods, the Onrust 2008/2010 publication exhibits appropriate reporting quality. The Routasalo 2009 / Pitkala 2009 / 2011 publication does not provide any information on perspective. Additionally, it lacks information and calculations on thresholds.

Both studies described the included benefit parameters or clinical parameters. No reasoning was provided as to why these parameters were chosen.

Neither of the 2 studies reports the resources used by the study population in the intervention versus control groups. Onrust 2008/2010 included direct medical and nonmedical costs and reports the prices and survey methods used. Additionally, it described the intervention costs. Routasalo 2009 / Pitkala 2009 / 2011 reported only some of the direct medical costs and underlying prices. Additionally, Routasalo 2009 / Pitkala 2009 / 2011 lacks detailed information on the calculation of intervention costs.

Transferability

The Onrust 2008 / 2010 and Routasalo 2009 / Pitkala 2009 / 2011 studies were conducted in the Netherlands and Finland, respectively, and reflect the research question of this HTA report. The Dutch study includes individuals as young as age 55 years and older. However, the mean age of 69 years (range from 50 to 92 years) corresponds to the target group of the HTA report. The assessment of transferability to the German healthcare system is complicated by the fact that neither publication reported resource consumption. Further, Onrust 2008/2010 takes a societal perspective and includes participants' time consumption. The assessment of transferability of the Finnish study Routasalo 2009 / Pitkala 2009 / 2011 is further complicated by the fact that no information is provided on the perspective taken. For both studies, the transferability of the employed prices and costs appears unclear due to differences between healthcare systems and cost structures.

6 Results: Ethical, social, legal, and organizational aspects

6.1 Results on ethical aspects

The scoping search found 12 relevant publications (see A9.3.1 List of publications included on ethical aspects). After additionally taking into account the theoretical reflection and information from interviews with people affected by social isolation and loneliness as well as volunteers, a total of 25 ethical aspects were identified. They can be allocated to ethical principles as follows: beneficence (n = 5), nonmaleficence (n = 9), autonomy (n = 5), justice (n = 5), and human dignity (n = 1).

From the ethical aspects, 7 assessment criteria were developed for interventions tackling social isolation and loneliness in the elderly. Aspects disregarded in this context were discussed in an ethical preamble (see A5.2.3). The wording of the 7 criteria listed below was discussed and adopted on the occasion of a stakeholder workshop and by written circulation procedure. Five criteria were rated as highly relevant for the German healthcare context, while among the remaining ones, 1 criterion was deemed relevant and 1 partially relevant.

At the outset, it must be noted that the objective situation of living alone can represent a major burden – if the affected people (subjectively) feel lonely. However, the situation is not necessarily associated with subjective suffering. The preferences of affected people with regard to interventions may differ just as much and must be taken into account.

In addition, changes to their immediate environment may cause affected people to feel as though they are no longer part of it; this is difficult to change but should be discussed.

Three “highly relevant” criteria are “rather critical” from an ethical perspective:

1) Introduction and sustainability

Funding insecurities due to time-limited project funds/grants represent a particular problem for interventions tackling social isolation and loneliness. In addition, the general conditions for offering interventions differ greatly across Germany (e.g. rural versus urban areas, networking, degree of organization, or staff/financial resources), leading to differing opportunities for implementation within the country.

2) Needs assessment and the “silent elderly”

The popularity of the offered services could lead to the impression that needs have been met. This may be a misperception because interest levels are very high even among people who are affected/suffering to a lesser degree, and the “silent elderly” staying home may be easily forgotten.

3) Raising awareness of offered services

Awareness of interventions/services is often spread through word of mouth. As a result, interventions run a risk of persons with very limited social contacts not finding out about them. The need or demand for interventions/services is very high, but it is particularly people who are affected less severely who express need, demand services, and take advantage of programmes. This circumstance can lead to the interventions not reaching the “silent”, lonely elderly whose needs are particularly severe.

Two criteria were rated as “partially critical” and at least “partially relevant”:

4) User-oriented services

Affected people may have different preferences and interests, which may be met in particular by offering options or specific local services. While in large cities, appropriate services are often available for particular target groups, it is more difficult to implement them in rural areas (far smaller number of services and less choice).

5) Consideration of causes

During an intervention, it is often impossible to address the causes of social isolation and loneliness such as disease or health limitations, e.g. because the staff are not appropriately qualified. Ideally, network structures have already been established through which affected people can be referred and receive comprehensive care. Establishing and maintaining these structures requires continuous work and attention. Another potential disadvantage is that social isolation is not classified as a disorder, while some of the causes of the phenomenon are deemed disorders. This can result in remits being unclear, which can complicate the establishment of long-term structures and programmes.

Two criteria were deemed “highly relevant” but “rather noncritical”:

6) Distinguishing technical/organizational barriers from social/psychological barriers

An intervention’s success is affected by aspects of both dimensions. Practical experience has also shown that it is essential for services to be low threshold, i.e. conveniently located and needs-adapted. The various interventions typically take this into account.

7) Good fit between staff and target group

Interventions are better accepted when affected people and staff members have similar social identities (language, culture, social experiences). In this context, it is easier to take into account larger minority groups, e.g. Turkish-speaking affected people, or people with special characteristics, e.g. “recently widowed”; some services also take into account sexual orientation.

6.2 Results on social and organizational aspects

The scoping search found 9 relevant publications (see A9.3.2 List of publications included on social and organizational aspects). The extracted information served as the basis for 2 interviews with people affected by social isolation and loneliness, an interview with a person volunteering in elderly care as well as the discussion on social, legal, and organizational aspects with professionals from the social assistance system within the stakeholder workshop. Additionally, social and/or organizational aspects were successfully extracted from all study publications included in the benefit assessment.

The results are presented based on the comprehensive conceptual framework suggested by Mozygemba 2016 [58] and are found in Figure 1.

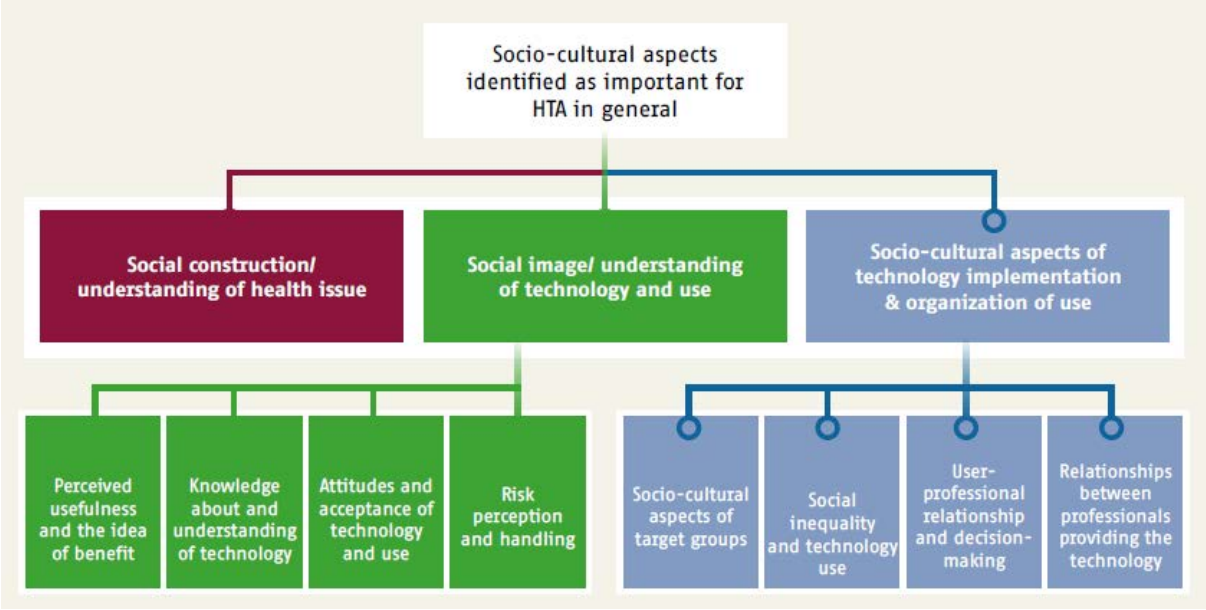

Figure 1: Social and organizational aspects of interventions tackling social isolation and loneliness based on Mozygemba 2016

6.2.1 Social construct / perception of social isolation

The construct of social isolation has not been clearly defined. It is used to describe a condition of objective isolation or lack of social integration which is measured by the quantity of social contacts. Loneliness describes the subjectively perceived social isolation which results from the individual assessment of the number, quality, and unmet need for contact. But being alone does not necessarily mean that you feel alone [3].

Social isolation and loneliness are not disorders but situations in life in which health status and functionality may be impaired by lack of participation [3]. Social isolation and loneliness increase affected people's morbidity and mortality. The surveyed affected people particularly reported affective and cognitive impairment resulting from lack of communication and

support. The focus was on depressive symptoms, the feeling of no longer being needed, anxiety, lack of drive, declining memory function, gastric symptoms, headaches, heart problems, and panic attacks. Affected people reported that, when people can no longer leave their homes, mobilisation and physical performance can severely decline. Social isolation and loneliness can further increase as a result.

Social isolation and loneliness were deemed by some affected people to be a normal part of ageing and were frequently experienced as socially stigmatizing because they are being attributed to personal failures. This may reduce both the willingness to admit feeling lonely as well as the acceptance of interventions. Affected people reported that they initially did not have the courage to take advantage of services.

6.2.2 Social image / perception of the intervention and its utilization

Perceived usefulness and concept of how benefit develops

Affected people primarily expected interventions tackling social isolation and loneliness to initiate new contacts and to thereby result in communicative exchange. To them, it was important that the decrease in feelings of loneliness lifted their mood. New contacts were also expected to strengthen their understanding of other people's life circumstances and their willingness to support and be there for each other. One volunteer working in elderly care described the success of interventions as potentially stemming from the fact that participants became more open again and actively participated in conversations. In addition, they reportedly regained more pleasure and interest in activities and exhibited improved language behaviour and mobility.

The interviewed affected people rated the effectiveness of interventions tackling social isolation highest when interventions took place in groups promoting specific topics and activities. This was in line with the identified key aspects from the scoping search, according to which proactive group interventions were deemed most effective against social isolation and loneliness [44,85,86]. According to the respondents from 1 study found in the scoping search [87], the most important benefits of participation in activities were based on their impact on mental health. They were described in terms of psychological benefits and social support: Psychological benefits were described as "fun", "feeling safe", "increased self-confidence", and "the value of learning new skills and using existing ones". The benefits of social support can be summarized as "friendship and companionship", "company", "care", "mutual benefit", and "reciprocity". For many older people, "pleasure" was the main reason for participating in activities, whether in groups or alone. Having company was described as the opposite of being alone and was often associated with pleasure. Social activities were something to look forward to and a reason to get up in the morning. Groups were often referred to as "lifelines" [87]. This view is consistent with the assessment by professionals in

the social assistance system, as expressed in the stakeholder workshop as well as the interventions in several included studies [88].

From the point of view of the interviewed affected persons and in the opinion of the professional stakeholders from the social assistance system who participated in the stakeholder workshop, health-relevant outcomes are not directly associated with the interventions tackling social isolation and loneliness. To them, it is first and foremost a matter of an assumed need for encounters at the local level, and the opportunity taken to have these encounters is therefore understood to be the goal. In their view, the principle of empowerment should be emphasized, especially in the case of professional services so that participants learn to establish and maintain contacts on their own.

Some studies found in the scoping search [43,44,85] and most of the studies included in the benefit assessment [62,63,66,67,72,74-76] (as well as in the interviews with affected persons and the professional stakeholders of the social assistance system) emphasize that interventions tackling social isolation and loneliness must be locally adaptable and optimally should be developed locally in collaboration with affected persons. These prerequisites for interventions are likewise expressed in the interviews with affected persons and professionals from the social assistance system. In large cities, for example, meeting places for senior citizens should be staffed differently depending on the neighbourhood to reflect sociocultural characteristics. In the context of the intervention studies examined, however, this requirement results in pronounced methodological challenges in terms of measurability. Having different services offered in various settings increases the degree of complexity and complicates the comparison of interventions within the evaluation. Therefore, highest possible target group orientation was usually operationalized as a limited selection of 2 to 4 offered programmes (excursions, painting courses, exercise programmes, etc.) or open planning of group activities [62,67,74-76]. Moreover, several studies focused on special target groups right from the outset, e.g. widowed [70,71] or relocated [63] persons, who were then to be enabled by targeted intervention to better cope with the situation in order to reduce social isolation and loneliness.

One study included in the benefit assessment aimed to enable the elderly to maintain and establish social contacts by teaching them technical skills [67]. However, it showed no statistically significant or relevant effect on health-related outcomes and resulted only in improved technical skills, which were also the main motivation for the elderly to participate.

Knowledge about and perception of the interventions

It was consistent with the general understanding of interviewed affected people that being part of a group can in itself mitigate social isolation and loneliness. This perception is confirmed by 2 of the intervention studies included in the benefit assessment: In these

studies, the group activity itself was not necessarily decisive for success [66,74]. Only very few of the included studies deemed their activity content, e.g. Tai Chi Qigong [59] or IT training [67], in itself as the key to reduce social isolation and/or loneliness Most of the concepts were based on the assumption that a group activity serves as the community-generating stimulus [76]. Group activities which also include physical activity elements, e.g. Nordic walking [64], were also thought to improve the well-being of participants through increased fitness.

Affected people deemed confiding in peers or volunteers to be equally valuable, thereby equating the methodology and the objective. According to respondents, much of the social isolation and loneliness could be prevented if services and the offered support were flexible enough to meet individual needs.

The success of interventions may also depend on the causes of social isolation and loneliness. These causes influence the willingness and ability to participate and were therefore in part taken into account in the interventions [73]. Loneliness may be related to the loss of a trusted person and the resulting grief, lack of meaningful social relationships, dissatisfaction with existing relationships, existential questions, deficits in early attachment relationships, or shyness and anxiety in social situations. Thus, analysing personal psychological barriers and targeting self-efficacy may be valuable components of interventions tackling social isolation and loneliness [72]. The intervention studies generally aimed to control for factors such as sex, marital status, housing situation, income, health and functional status, or depression on the results via statistical adjustment methods [89].

Thirteen studies included in the benefit assessment relied on theory-based approaches. For example, Heller 1991 describes that social support buffers social stressors so that they have an attenuated emotional intensity and effect on the individual. Persons or groups with whom concerns or problems are discussed can thus reduce the emotional intensity of these issues. In addition, this impact model assumes that people in social relationships generally behave in a more health-promoting manner [68]. Zhang 2019 was the only study to explicitly attempt to use the initiation of group opportunities to have developing friendships compensate for a lack of family support. The hope was that new acquaintances would also provide support in the event of illness or need for long-term care [65].

Focusing on possible ecological impacts, Ristolainen 2020 formulates the hope that local mediation of social support could also strengthen basic trust in local and institutional structures.

Attitudes toward and acceptance of interventions

The interviewed affected people were particularly receptive to professionally led group interventions to initiate contact, experiences, and educational content. They most appreciated programmes involving playing games, singing together, eating together, taking

excursions to other cities and towns, and visiting exhibitions. Additionally, they rated support with everyday living as a useful service which should be offered nationwide when people need support or suffer from social isolation and loneliness.

The experienced interventions tackling social isolation and loneliness generally met with a very high level of acceptance among the interviewed affected persons. They believed that those affected should be especially there for each other. In the context of this HTA, however, only people who participated in interventions tackling social isolation and loneliness were interviewed. Professionals from the stakeholder workshop likewise attested a very high reputation to interventions tackling social isolation and loneliness. However, they also observed that some services offered by the social welfare office are not utilized because of these offices' negative connotations. In their opinion, some services may also embarrass affected people because they may experience themselves as recipients of help who can offer nothing in return. Various publications likewise emphasize this aspect of reciprocity [44,60]. Therefore, programmes involving people who are affected by the same issue and can provide mutual support appear to be particularly well accepted [66,71]. For those affected, the desire to maintain their independence, autonomy, and control is of central importance. Rather than being patronized, they want to feel valued for their contributions and to be viewed as a resource rather than a burden [87].

Despite the general assessment that group services are the most promising, it is very difficult for some affected individuals to initially participate in a group. Several studies included in the benefit assessment responded to this issue by developing/testing staged interventions. In these studies, affected individuals were first prepared for group processes and equipped with the necessary skills in one-on-one sessions [60,61,65,68,72].

Furthermore, it is noted that a programme's participation rate is not by itself a sufficient acceptance and quality criterion. Oftentimes, no suitable activities are available and accessible, resulting in some affected people settling for activities which do not meet their needs [87].

The professionals from the social assistance system who participated in the stakeholder workshop also emphasized that the majority of elderly people in Germany have never visited a senior citizen gathering. They perceive most elderly people as being very independent and, in this context, described a "rejuvenation of old age" when compared to the 1980s: "today's 80-year-olds are like the 60-year-olds back then". This group of people does not see itself as old and therefore does not feel the need for appropriate services. The professionals from the social assistance system reemphasize that social isolation alone does not cause loneliness but must be accompanied by subjective suffering.

Risk perception and handling

Personal risks which might arise from participation in an intervention were not mentioned in any of the interviews nor in virtually any of the studies included in the analysis of social and organizational aspects of interventions tackling social isolation and loneliness. Only 1 intervention study describes that the researchers felt it very important to exclude persons without feelings of loneliness to avoid evoking feelings of loneliness in these persons through the discussion of this topic [90].

6.2.3 Sociocultural and organizational aspects of the interventions

The interviewed affected people reported on interventions conducted by a mobile nursing service in Schleswig-Holstein as well as on various services offered by a senior citizens' counselling centre, which were set up by the Hamburg social authority as well as financed by public funds. The social care service called *Sozialstation* belongs to one of the large welfare associations and offers nursing care services as well as social services within the scope of SGB XII Assistance for the Elderly. Reported were different leisure activities performed in groups, a regular dinner meet, a breakfast meet as well as a half-day meet. In addition to the shared meal, the focus is on communicating as well as playing games, singing together and, less frequently, doing physical exercises. In addition, those affected emphasized the importance of joint excursions, which are also offered by the mobile nursing service and arranged by the senior citizens' counselling service. These particularly involve bus tours to ever new destinations including guided tours and meals.

Likewise, professionals from a senior citizens' counselling centre and from the staff of a large welfare organization reported at the stakeholder workshop on the popularity of senior citizens' holidays and group activities, most of which were based on Section 71 of Social Code Book XII, Assistance for the Elderly. With regard to the studies included in the benefit assessment, the professionals from the social assistance system emphasized in the stakeholder workshop that all interventions investigated in the studies are already or might be implemented in the German structures via SGB V, IX, XI and XII as well as via the large number of institutions. They deem the differentiation between preventive and therapeutic approaches to be of little use and not to hold up in practice. It would reportedly be more useful to address different intensities of social problems.

The interventions in the studies included in the benefit assessment were largely conducted in existing facilities in German communities, which is why transferability seems possible in this regard as well. The studies were conducted in a day care facility [74-76], in a type of community centre [63-65,73], in a social counselling centre [72], in a gym [73], in a library [73], at the affected people's private homes [67,70,71], or were undertaken in writing [66] or by telephone [66].

Sociocultural aspects of the target group

With regard to the different sociocultural groups in the studies included for the benefit assessment and on the basis of their professional experience, the professionals from the social assistance system emphasized during the stakeholder workshop that the composition of the population may vary greatly from region to region in terms of demographic, socioeconomic, and ethnic and cultural characteristics. Therefore, they believe that, for all interventions tackling social isolation and loneliness in the elderly, it is essential that a facility's services be culturally sensitive and needs adapted. In the scoping search on social and organizational aspects of interventions tackling social isolation and loneliness, adaptability to the local context was equally identified as a key element for the success of an intervention. Interventions are most promising when they are implemented and adapted together with all stakeholders in the community [44].

It can be noted that all interventions from the studies included in this HTA exist in a similar form in various locations in Germany (stakeholder workshop). However, since the experiences and causes of loneliness always vary among individuals, difficulties may arise when adopting standardized programmes from different contexts. It is therefore recommended to evaluate individual needs in the early intervention phase in order to tailor interventions to specific groups or individuals [43].

Participants in the included studies also largely correspond to the target group which was focused on in Germany by the Social Code, social welfare centres, and counselling centres for seniors in terms of interventions tackling social isolation and loneliness in the elderly. Participants in the included studies were over 60 years, 65 years [59,62,64,66,67], or 75 years of age [60,73], respectively. Most studies excluded manifest cognitive diseases such as dementia or psychosis. Due to their age, some participants had mild cognitive impairments, mobility limitations, and various chronic diseases (compare tables of studies' inclusion and exclusion criteria in A3.2.1.2 and A3.2.2.2 of the full report).

Some studies included in the benefit assessment addressed target groups which slightly differed from those described above: For example, the Onrust 2008 / 2010 study examined a programme targeting people over age 55 years who had lost a partner in the past 6 to 9 months. Heller 1991 investigated a programme for low-income women; MacIntyre 1999 tested a programme for immobile persons; Saito 2012 studied a programme for older people who had relocated; and Zhang 2019 studied a programme targeting people without children or whose children had moved away and who thus lacked support.

In a few studies, the target group also included the participants' social network. They operate under the hypothesis that interventions are more successful if they involve resources from the neighbourhood to create a sense of companionship and activity and a sense of belonging

in the local area [44]. Fields 2020 participants were to gain skills to stay in touch with their network or establish contacts with new people via tablet and internet training. Chan 2017 aimed for people to meet new people in the neighbourhood through specific matching procedures, and part of the objective of Ristolainen 2020 was to gain access to professional support networks.

With regard to the reasons motivating people to participate in studies with interventions tackling social isolation and loneliness, the qualitative research by Hind 2014 / Mountain 2014 showed an interesting result: Some participants emphasized that they participated mainly to help the study team, other affected people, or future affected people.

At the stakeholder workshop, it became clear that professionals from the social assistance system strongly believed that the ultimate goal must be to establish contacts and that the content of individual measures is of lesser importance. From their point of view, the most important aspect is to offer a wide diversity of services close to home in terms of the services' locations, times, contents, and target groups. The common denominator should be that these offers (a) are low threshold, (b) can meet specific existing needs, and (c) are designed to last. They argue that especially elderly people who are affected by social isolation and loneliness are not able to move from one project to the next.

To the interviewed affected persons, it was also important that the services be designed to be participatory and needs-oriented. From their point of view, both one-on-one discussions taking place during visits to the private homes of affected people and group activities are justified, depending on needs. In terms of group activities, affected people expressed preferences for excursions, memory exercises, "coffee klatch," board and card games, and singing old songs. They were more reserved regarding light physical exercises and religious topics. Interviewed affected people said that it was important to always offer a choice of different topics within a group. In some intervention studies, programmes with physical activity were very well received [59,73], but they should take into account different fitness levels [64]. Two of the included studies additionally addressed topics such as doing puzzles together, using social services, financial counselling, arranging for measures to be taken in the home, arranging for nursing and medical services, and arranging for neighbourhood activities [72]. Moreover, the scoping search for social and organizational aspects of interventions tackling social isolation and loneliness showed that interventions should preferably have a productive element through which participants can experience or develop something [44].

In a qualitative investigation, Cattan 2003 divided participants into 2 groups. Participants were distinguished by how they dealt with loneliness and social isolation. Older people who joined groups, the "active lonely," had often led active lives, had been employed, and had cared for families. Many described their need for continuous social contact, for the feeling of being needed and respected, and for taking charge of their own lives. The other group, the "inactive

lonely", is often the intended target group for interventions tackling social isolation and loneliness. They consist of the frail elderly who have led a less active life so far. This target group is often hard to reach [87].

Generally, the interviewed affected people were most concerned about an "unnatural" atmosphere which could easily arise in a staged group as well as in one-on-one conversations and would deter potential participants. Similarly, some participants in a study included in the benefit assessment expressed that they had been very apprehensive about simply calling someone who was a complete stranger [68]. In the Hind 2014 / Mountain 2014 study, participants in a group intervention conducted by telephone reported that it was difficult to speak up because they always felt they would interrupt someone or were afraid that everyone would suddenly speak at once. Participants in another study (Ristolainen 2020) complained in this context that no camaraderie or naturalness developed if group members changed frequently or the intervals between meetings were too long. Participants in this study were very concerned that they would not know what to talk about with the other people if they did not know each other [62]. Participants in the Hind 2014 / Mountain 2014 study also reported in this regard that they did not feel like delving into topics that did not interest them. One aspect mentioned in the study was that a desire for evening programmes was expressed by some, but that such programmes were never available [72]. Overall, the included studies with group interventions attempted to maximize group homogeneity to ensure that they ran as harmoniously as possible [74-76].

Aspects of social inequality in the utilization of interventions

Professionals from the social assistance system reported that, especially in metropolitan senior centres, participants of in interventions tackling social isolation and loneliness were very culturally diverse. Therefore, staff members regularly receive intercultural training. According to the interviewed professionals, however, especially very old people have difficulties with cultural diversity. Furthermore, there is always an elevated risk of overlooking minorities in a neighbourhood. In order to minimize social inequalities, the low-threshold nature and accessibility of services are of central importance. The way out of isolation and/or loneliness can only be found close to home. Services should be customized and based on a comprehensive needs analysis that covers all population groups. As is the case in all social spheres, the density of services and hence the diversity of services is much lower in rural areas. The professionals conclude that this makes it more difficult for affected people to find and utilize services.

All interviewed affected people emphasized that any costs or cost-sharing must be socially acceptable so that no one is excluded. It was also important to them that people can get to and from all services. Otherwise, vulnerable groups with impaired mobility or financial limitations, in particular, would be systematically excluded from interventions tackling social

isolation and loneliness. This especially applies to residents of rural areas who do not have their own means of transport. The professionals from the social assistance system stated that it is generally possible for social services to assume the costs if a need is identified. Theoretically, the contacting authorities inform social welfare offices of the affected people's need for services, and the social welfare offices take action automatically. In practice, however, people in need of assistance usually have to take action themselves in order to receive benefits. Only in some cases can outreach work be initiated through the regular channels.

The intervention studies included in the benefit assessment did not charge any fees for study participation and provided transportation by minibus [62,74-76] or the required Internet access [67] if needed. If no transportation was provided, disadvantaged, burdened persons stayed away from the services, and only relatively healthy older people participated [64]. According to the interviewed professionals from the social assistance system, for standard benefits, the cost coverage must be clarified via the Social Code Books if the income of a person would prevent him or her from participating.

To avoid social inequalities, sociodemographic factors such as age, poverty, and need for long-term care, the social environment, i.e. access to transport, driver's license status, and place of residence, as well as physical and mental health should always be taken into account (Fakoya 2020). Fakoya further noted that primary research on social isolation and loneliness has predominantly focused on the female population. Interventions therefore often focus on female interests [43,85]. Some authors cite this circumstance to explain the typically higher participation rates of women in the included intervention studies [66,72]. Overall, it was found that the needs of less researched groups were rarely taken into account. People with physical disabilities, ethnic minorities, family caregivers, recent immigrants, people with hearing and visual impairments, people who have been isolated for a long time, and older men are often not addressed or excluded by interventions [43,87]. Furthermore, it was noted by Courtin 2017 that intervention studies rarely include sufficient subgroup analyses for a nuanced evaluation of effectiveness [91].

Publications found in the scoping search on social and organizational aspects of interventions tackling social isolation and loneliness found an indication of a core group of articulate, mainly middle-class, reasonably fit, "active lonely" older people with active social networks being more likely to participate in activities than frail, less active older people. However, the latter are usually the originally intended target group [60,87]. Older people with poorer quality of life are more difficult to reach, and they are also less likely to participate in intervention studies [62]. People at higher risk of loneliness also have lower self-confidence and thus little motivation to respond to an invitation [64]. In addition, people with more disabilities who required assistance with ambulation, had dementia, lived in nursing facilities, or had severe

heart failure were more often excluded [63,68,74-76]. Simultaneously, people with more severe health limitations dropped out of interventions more frequently [67,72,73].

On the other hand, intervention studies with a preventive approach may find it difficult to recruit or attract study participants if they see themselves as having little need for support and thus no need to participate [60]. Onrust 2008 / 2010 showed that only particularly disadvantaged groups benefited from the intervention, while widowed individuals with low loneliness scores at baseline and existing social support showed no effect. For interventions which sought to build purely technical skills, such as maintaining contacts via the Internet or directly arranging caregiver support in the neighbourhood, the authors report a perpetuation of inequality. People who had no previous contacts or support were also unable to establish new contacts through new communication opportunities [67] or nevertheless felt subjectively unsupported by the pertinent support services [65].

Last but not least, an urban-rural divide emerged when measures were examined in both regions. In places with a less differentiated infrastructure, it was impossible to offer all services [62,74-76].

It should also be noted that visiting services or telephone services enabled access for physically ill persons or persons with functional disabilities, while group services place higher demands on the participants [68,70,71].

Aspects of intervention advertising and outreach

Recognizing that it is difficult to reach older people with poor quality of life is important for successfully implementing interventions. These people are more likely not to participate in interventions [62], as are people who cannot articulate themselves very well [87]. The interviewed affected people also discussed this risk and suggested that interventions should be widely advertised. As a low-threshold measure, for example, brochures could be displayed in medical waiting rooms and pharmacies because this is where withdrawn older people might be reached. Moreover, placing brochures directly into mailboxes was described as a promising method as well. The 2 interviewees thought it was most crucial that potentially lonely people be addressed personally. In their view, staff in general practitioner’s offices should pay more attention to whether someone is lonely and then refer them to suitable interventions as needed. Likewise, the awareness of social care services and church associations could be increased. Publication via advertisements in newspapers or bulletin boards may be a supplementary method but should never be the only one.

During the stakeholder workshop, the professionals from the social assistance system likewise referred to advertising materials in the outpatient and inpatient medical/nursing sector. In addition, efforts are reportedly made to advertise interventions on various Internet platforms. Cooperation with general practitioner’s offices is deemed to be important but not yet

sufficiently implemented. Essentially, the professionals believe that services are generally advertised and addressed based on the peer-to-peer principle. Senior counselling centres, for example, are decades old and well-known in the neighbourhood. Therefore, word-of-mouth marketing works best. This was also confirmed by interviews with affected people from the Cattan 2003 study, where word-of-mouth was the most common route to an activity.

Respondents in the Cattan 2003 study also pointed out that it is important for services and interventions not to conceive of older people as homogeneous groups. It should not be assumed that all older people want to engage in activities to alleviate social isolation and loneliness. Some of them may have always been "private people", or they may have gradually withdrawn from society later in life.

The recognition that it is potentially difficult for interventions to reach older people affected by social isolation and loneliness was also evident in the recruitment results of many of the intervention studies included in the benefit assessment. Participation rates of 1.6% [60], approximately 3% [74-76], 8% to 10% [63,70,71], and 20% [73] were calculated, e.g. with the aid of local registry data. Intervention studies which used broad, unsystematic recruitment strategies such as notices in senior centres, flyers in public buildings, lectures in public universities, radio advertisements, newspaper advertisements, brochures in pharmacies and local health centres were unable to calculate a specific participation rate [60,62,64,72]. One study called all women in a low-socioeconomic-status neighbourhood and recruited them as needed. However, it was impossible to calculate a participation rate because the total population was not reported [68]. In addition to the recruitment routes already mentioned, some intervention studies included only participants who were previously enrolled in a corresponding organization for older people [67] or who were already in a research database [60]. Care managers and experts from smaller, local nonprofit organizations were also used [62].

Based on the peer-to-peer principle, another study attempted to recruit not only participants but also volunteers who would then implement the interventions [59,60]. The basic prerequisite for this type of intervention is cooperation with large volunteer organizations (Caritas, German Red Cross, etc.). If volunteers can be recruited, it may be possible at the same time to use them and their social networks for recruitment, although it was emphasized that no social pressure should be exerted to persuade potential participants [59].

Aspects of the professional relationship between providers and affected persons

According to the professionals from the social assistance system, interventions tackling social isolation and loneliness in the elderly are typically organized and provided by a combination of volunteers and employees. The proportion of volunteers in the services offered increases with a neighbourhood’s SES. While senior citizens' meetings in affluent neighbourhoods are

usually run by senior volunteers, more social education workers are employed in low-SES neighbourhoods. In these neighbourhoods, the services also tend to be of a socially counselling nature, while services in affluent areas have more of a recreational character.

The interviewed affected people reported exclusively on activities with a recreational character and on the involvement of volunteers. The boundary between providers and participants is sometimes blurred because, as reported in the interviews, volunteers are often also people affected by loneliness who simultaneously take on responsibilities and provide services. Many interventions therefore also exhibit the character of a self-help group in which there are no institutional hierarchies. At the same time, this results in no claim to professionalism or to fixed quality criteria. For example, volunteer facilitators in 1 study (Hind 2014 / Mountain 2014) differed greatly in their management of group processes. Some were very “hands off” in terms of how they ran the group, while others "strictly intervened."

At the same time, the blurring of the boundary between affected people and those providing assistance enables low-threshold interaction at eye level, even for people with very low self-esteem and very little contact with the outside world [60,63,66,69-71,87]. Chan 2017 showed that the proximity between matched volunteers and the elderly can create a sense of neighbourliness, where peer relationships would make immediate help available when needed. As outlined by the professionals from the social assistance system, these interventions were conducted by a mix of professionals and volunteers. The professionals primarily organized the recruitment and training of volunteers and the fit with participants [59,63,65-67,69,73]. Respondents from 1 study found in the scoping search emphasized the importance of reciprocity in the relationship between volunteers and older people affected by social isolation and loneliness, pointing out that a similar age, culture, and social background contribute to the success of the service [87]. Moreover, volunteers in other life settings or life stages, such as those who visited older people as part of their gerontology studies, were also able to demonstrate good pairing [69].

Recruiting, organizing, and training volunteers can be very taxing for professionals because volunteers usually have many other obligations and may be less dependable than staff members. In those cases, delays and bottlenecks may arise in the provision of interventions [60,66]. The provision of the intervention is thus always characterized by some impasses. The professionals from the social assistance system additionally pointed out that concrete (and measurable) health-relevant outcomes are not usually the focus when developing and planning interventions. In most cases, a need is assumed, which is then to be met by a service. The focus is on participation and the associated contentment. The goal of empowerment is usually pursued by professional social work services. They strive to enable people who are affected by loneliness to establish or maintain contacts independently.

The professionals from the social assistance system (stakeholder workshop) and the reviewed literature reported little about cooperation between different professions and with different professional cultures. But there seems to be a general perception among the interviewed professionals that social isolation has both medical and social implications and that therefore, health and social systems should work together to address these issues.

6.3 Results on legal aspects

6.3.1 Introduction

Social isolation in the elderly is a phenomenon which has been only rudimentarily juridified. For instance, no social isolation insurance exists to cover the consequences of old age as such. However, German social and health law offers possibilities for countering the risk of social isolation in the elderly by legal control mechanisms. Social isolation in the elderly affects at least indirectly the risk areas of several social law systems. Socially isolated elderly people are no longer in the labour force and may not possess sufficient wealth. In addition to these financial risks, the risk of falling ill or requiring long-term care also increases in the elderly. These risks associated with increasing age can be mitigated by the German social and health care law in various ways, namely through financial transfers and health-related benefits in kind.

This report does not take into account cases in which elderly people are permanently physically or mentally impaired in addition to facing (imminent) social isolation in the elderly. According to the report concept, social isolation in the elderly is understood as an overall social phenomenon which typically accompanies old age and therefore does not represent an exceptional health situation which requires intervention according to the law on the rehabilitation and participation of disabled people (Section 2(1) sentence 2 SGB IX).

Areas of social law touched upon

Particularly for older insured persons who are no longer gainfully employed (see Sections 9, 10 SGB VI), the statutory pension insurance (SGB VI) and social assistance (SGB XII) provide financial transfer benefits, namely pension payments (Sections 33 et seq. SGB VI), assistance for livelihood (Sections 27 et seq. SGB XII), and basic security for the elderly (Sections 41 et seq. SGB XII). The law on social assistance explicitly contains a principle of priority, according to which cash benefits generally take precedence over benefits in kind; nevertheless, social assistance benefits can also be provided as benefits in kind (Section 10 (3) SGB XII). Of particular relevance in the context of this report is assistance for the elderly (Section 71 SGB XII).

Statutory health insurance (SGB V) and social long-term care insurance (SGB XI) are characterized more strongly by the principle of payment in kind. In order to maintain or restore the health of the insured or to improve their state of health (Section 1 sentence 1

SGB V) or to provide assistance to those in need of long-term care who are dependent on support due to the severity of their need for long-term care (Section 1 (4) SGB XI), the health and long-term care insurance funds generally provide their benefits in the form of benefits in kind and services (Section 2 (2) SGB V, Section 4 (1) SGB XI). The health insurance funds are furthermore the central entities responsible for prevention and health promotion – with the long-term care insurance funds only being responsible for this in the special area of inpatient care facilities – (Section 5 SGB XI), including for implementing the health goal of "healthy ageing" (Section 20 (3) Sentence 1 no. 7 SGB V), which they can pursue through behavioural prevention in individual cases (Section 20 (5) SGB V) or through prevention programmes in the home and leisure environments (Section 20a (1) SGB V) [92].

In line with the interventions evaluated in this report, the legal investigation will focus on aspects of benefits in kind and look at the systems of SGB V and SGB XI as well as social assistance (SGB XII), including the so-called public services in the municipalities (cities and communities) as well as the independent welfare care supported by church and other non-profit institutions.

Social security insurance as a safety net protecting against specific risks

The prevention and reduction of social isolation in the elderly through social insurance, particularly health insurance, is currently more of a reflex of the regulations rather than being intended as their main purpose. This follows from the fact that social security insurance is always linked to life risks which go beyond (potential) social isolation in the elderly, namely illness, need for long-term care, disability, and incapacity to work (including due to age). This link to specific risks is legally mandatory because social security insurance benefits are generally to be financed by contributions from its members – and supplemented by subsidies from the federal government (see Section 150 SGB III, Section 20 (1) SGB IV, Sections 3 sentence 1, 220 (1) SGB V, Section 153 (2) SGB VI, Section 150 (1) SGB VII, Section 54 (1) SGB XI). The reason for levying contributions must therefore be linked to the purpose for which they are used; unlike taxes, social security insurance contributions may not be freely used for just any purpose. Health insurance contributions must not be used for anything other than funding health care services, and long-term care insurance contributions must be used to fund only long-term care services [93]. However, not subject to this earmarking is social assistance, which is funded by taxes rather than contributions, in this context especially in the form of assistance for the elderly (Section 71 SGB XII).

The above structures must be taken into account when examining interventions to tackle social isolation in the elderly. For example, preventive interventions paid for by contributions from health insurance funds must also serve the goal of helping insured persons grow older in good health (Section 20 (3) sentence 1 no. 7 SGB V) and hence aim at disease prevention. A disease in that sense is defined as an abnormal physical or mental condition which results in

the need for medical treatment or – simultaneously or separately – incapacity for work [94]. Social isolation in the elderly does not necessarily lead to a condition requiring treatment in that sense, but it is nevertheless associated with health risks, particularly with regard to depression, anxiety disorders, delusional disorders, the fostering of paranoia, and somatic and psychosomatic consequences (compare 1.2.2).

This report evaluated 2 different categories of interventions for social isolation in the elderly. The question is therefore whether and in what form legal footing for such interventions already exists in Germany or might exist in the future. To facilitate a purposeful analysis, the interventions examined in this HTA report can be divided into 2 types, i.e.

- support services (interventions) mainly implemented by volunteers and
- support services (interventions) mainly implemented by trained, paid staff.

6.3.2 Current social and health care law

The following section examines the extent to which current social and health care law already provides for the interventions examined as services for the elderly and what changes are necessary.

Volunteer visiting services for the elderly

Role of the nonstatutory welfare sector

Visiting services are currently offered at a low-threshold level primarily by volunteers from the nonstatutory welfare sector (see Section 5 (1) SGB XII). Services vary between different municipalities and cities, and no comprehensive overview of services can be found [95-98]. These visiting services are financed by donations and the organizations' membership fees.

Role of long-term care insurance

Several years ago, the social long-term care insurance system introduced the so-called services for support in everyday life (*Angebote zur Unterstützung im Alltag*, AUA benefits) Sections 45a-45d SGB XI. These are intended to relieve caregivers and help people in need of long-term care to remain in their home environment for as long as possible, to maintain social contacts, and to continue to be able to manage their everyday lives as independently as possible (Section 45a (1) sentence 1 SGB XI). Among other things, they serve to support persons in need of long-term care in coping with general or care-related requirements of everyday life (Section 45a (1) sentence 2 no. 3 SGB XI). This "everyday assistance" covers both professional visiting services and the arrangement of voluntary visiting services (see Section 45a (1) sentence 5 SGB XI) [99].

However, AUA benefits are not general citizen or elderly assistance benefits, but special benefits of long-term care insurance [98]. Consequently, the elderly people visited must be in

need of long-term care, i.e. they must exhibit health-related impairments to their autonomy or capabilities for at least 6 months and therefore require help from others; they must be people who cannot fully compensate for or cope with physical, cognitive, or psychological impairments or health-related stresses or demands (Section 14(1) SGB XI). When determining the need for long-term care, the focus is primarily on physical and psychopathological criteria (mobility, cognition, behavioural problems, self-care). The ability to organize everyday life and social contacts, including interaction with people in direct contact and maintaining contact with people outside the direct environment, is a criterion when assessing the need for long-term care (Section 14 (2) no. 6 SGB XI). However, this ability is only weighted at 15% in the overall assessment of the need for long-term care (Section 15 (2) sentence 8 no. 5 SGB XI), while the ability to care for oneself, for example, is weighted much more heavily at 40% (Section 15 (2) sentence 8 no. 5 SGB XI). In addition, the following abilities are included in the assessment: mobility at 10%, cognitive and communicative abilities as well as behaviour and psychological problems together at 15%; coping with and independently dealing with illness-related or treatment-related demands and burdens at 20% (Section 15 (2) sentence 8 nos. 1, 2, 4 SGB XI).

Therefore, even acute social isolation in the elderly does not by itself justify an entitlement to AUA benefits.

Role of social assistance, especially assistance for the elderly

Furthermore, social assistance in the form of assistance for the elderly provides exemplary benefits which enable the elderly to maintain contact with persons close to them (Section 71, subsection 2, no. 6, Social Code, Book XII). This concerns not only contacts to partners and relatives, but to any additional group of persons to which a special emotional connection exists [100,101]. The social welfare organizations are also called upon to provide such services if they serve to prepare for old age (Section 71 (3) SGB XII); assistance for the elderly is therefore not necessarily tied to reaching rigid age limits but can be provided preventively [101,102]. The responsibility can be structured differently in the German federal states. As a rule, districts and district-free cities are responsible at the local level (Section 3 (2) sentence 1 SGB XII). The overall aim of assistance for the elderly is to help prevent, overcome, or alleviate difficulties arising from old age and to give old people the opportunity to participate in the community in a self-determined manner and to strengthen their ability to help themselves (Section 71 (1) sentence 2 SGB XII). In line with this broad understanding of benefits, assistance for the elderly is to be provided in large parts even without regard to existing income or assets, which are typically taken into account in social assistance (Section 71 (4) SGB XII). Accordingly, the elderly do not necessarily have to be particularly "poor" to receive these benefits.

Volunteer visiting services for the elderly as found in Onrust 2008 / 2010 do not aim to establish a connection with previously close persons within the meaning of Section 71 (2) no. 6 SGB XII; instead, they are intended to first establish and deepen contact between the elderly and 1 or more other persons. Consequently, this intervention does not fall under the example of "connection care" according to Section 71 (2) no. 6 SGB XII. However, this does not preclude an allocation to the entire broad spectrum of elderly assistance services since the potential contents of services go far beyond the example services [103]. In addition to contact mediation, any travel or telecommunication costs, for example, may also be covered [104].

It should be noted, however, that according to Sections 17 (1) and 71 (1) SGB XII, the elderly are not generally entitled to specific services through assistance organizations for the elderly. In principle, therefore, they cannot directly demand that the social welfare agency provide the specific desired visiting service [105]. As worded in the provision, the social welfare agency "should" provide services for the elderly, but it may choose them at its discretion [106]. However, where the social welfare agency already grants specific benefits of assistance for the elderly in its ongoing administrative practice, it has committed itself, which can be condensed into a specific claim for the elderly, e.g. to a visiting service [105].

Assistance for the elderly is of extremely limited relevance in the current practice of applying the law and case law. On 7 May 2021, the Juris database recorded only 10 social court decisions on Section 71 SGB XII – compared to 1962 recorded court decisions on the basic benefit standard of health insurance (Section 27 SGB V), for instance. Only about 1% of recipients of assistance in special circumstances make use of it [107]. In 2011, only about 0.03% of the total expenditures on social assistance was spent on assistance for the elderly [108], and only once has a legal dispute from the area of assistance for the elderly reached the Federal Social Court. This ruling [109] clarified that the subsidiary entitlement to assistance for the elderly presupposes individualized age-related difficulties and that a person's age alone does not trigger entitlement to assistance for the elderly. The aim of assistance for the elderly in its current legal form is to cover additional needs arising from the physical, mental, or spiritual difficulties of old age [109]. Such needs include, in particular, (imminent) isolation and loneliness due to age-related reasons, e.g. after retirement or the loss of a partner [109]. Despite progressive demographic change, however, the provision still leads a "niche existence" even today [107] and cannot provide a basis for comprehensive legal policy concepts to help older people [109,110]. It has therefore been criticized for some time and is seen as requiring reform in order to better meet the special needs of older people now and in the future, especially across municipalities and sectors [107,111].

If a visiting service is already provided by the nonstatutory welfare sector, the statutory bodies with responsibility for social welfare should refrain from taking measures of their own

(Section 5 (4) sentence 1 SGB XII). This corresponds to the fundamental principle of subordination of social assistance (Section 2 (1) SGB XII).

Even under the current social and health law, it is therefore possible to implement the intervention of a volunteer visiting service via the instrument of assistance for the elderly. This does not require the elderly to have already been diagnosed with an illness due to social isolation.

Professional interventions in the form of group activities for the elderly

Regarding professional interventions in the form of group activities for the elderly, the current legal situation is essentially the same as that of volunteer visiting services.

Role of long-term care insurance

The long-term care insurance funds promote the establishment and expansion of self-help groups to support people in need of long-term care and their relatives and similarly close persons (Section 45d sentence 1 SGB XI). Such self-help groups aim to improve the living situation of persons in need of long-term care as well as their relatives and persons with comparable close ties through personal, mutual support, including with the aid of services provided by volunteers and other persons willing to engage in civic involvement (Section 45d sentence 13 SGB XI; compare also Section 45c (1) sentence 1 no. 2 SGB XI). In addition, the aforementioned services of support in everyday life (so-called AUA benefits) also include care services where those in need of long-term care can be looked after in groups in order to maintain social contacts (Section 45a (1) sentence 2 no. 1 SGB XI). Where the elderly are not in need of long-term care, however, social isolation in the elderly does not in itself give rise to an entitlement to corresponding services under current law. In Pitkala 2009 / 2011 and Routasalo 2009, the participating elderly were definitely not sufficiently physically or mentally impaired to be certified as needing a high level of long-term care under German law. Exclusion criteria for study participation were, e.g. moderate to severe dementia, long-term utilization of inpatient care, and (for certain activities) cardiovascular problems.

Role of social assistance, especially assistance for the elderly

In assistance for the elderly, there is already an explicit legal basis for professionally supervised group activities for the elderly, namely the benefit example in Section 71 (2) no. 5 SGB XII. Accordingly, "services for attending events or facilities which serve the sociability, entertainment, education, or cultural needs of the elderly" in particular are eligible as benefits of assistance for the elderly. This is intended to maintain, create, or reactivate a wider range of social contacts [112]. There is no dispute about the numerous types of group activities which are covered, such as entertainment afternoons, dance events, concerts, adult education courses, or excursions [112,113], and indeed also and especially those which are not

specifically or exclusively directed at older people (so-called open assistance for the elderly), so as not to exclude them from the rest of society [113-115].

Even under current social and health law, the intervention of professionally supervised group activities can be implemented via the instrument of assistance for the elderly. This does not require the elderly to have already been diagnosed with an illness due to social isolation.

6.3.3 Regulatory outlook and need for reform

No need for reform in the narrower sense

In light of the existing possibilities for assistance for the elderly which are enshrined in the law, there is no need for reform in the narrower sense regarding volunteer visiting services or group activities for the elderly. Nonetheless, the question arises as to whether the health and long-term care insurance funds could be more closely interlinked with the structures of municipal assistance for the elderly in order to counteract the risks of social isolation in the elderly.

Overall structural reform

An overall structural reform of assistance for the elderly toward a holistic policy for the elderly [111], which has been under discussion for some time and is to include visiting services and structures for group activities, would be another way forward but can only be accomplished at the macro level of legal policy. The comprehensive federal, state and local legal adjustments which this would cause cannot be foreseen at present.

Stronger interlinking of assistance for the elderly with health insurance funds

Prevention

What would already be legally conceivable even under the current system is to support the municipal bodies responsible for assistance for the elderly through prevention services paid for by the statutory health insurance in the areas of housing and leisure activities for the elderly (Section 20a (1) SGB V) [92]. To this end, the health insurance funds together with the public health service can, in particular, establish and promote health-promoting structures (Section 20a (1) sentence 2 SGB V) and provide their own prevention services (Section 20a (2) SGB V). These options would require no more than a sufficient link to disease prevention. Social isolation in the elderly does not necessarily cause diseases such as depression, anxiety disorders, etc., but it may increase the risk of such diseases. Strategies to prevent social isolation and loneliness in the elderly are therefore of sufficient preventive relevance [92]. Moreover, home visits provide an opportunity to assess further health needs of the visited elderly people [116].

If the health insurance funds and the bodies responsible for assistance for the elderly were to coordinate and provide interlinked, low-threshold services, double incentivization of the same

interventions would be prevented, which in turn is in the interest of clear (funding) responsibilities [92]. The options available to health insurance funds are versatile. In particular, cooperation may be established with community centres and senior citizens' centres as well as meeting places, housing associations, institutions of welfare organizations, religious communities, associations, or adult education centres [92]. These possible interventions from different living environments (such as housing and community life) can counteract social isolation in the elderly, particularly through personal contacts and group activities.

Selective contracts as an instrument for interlinking the funding bodies

This networked collaboration could also be legally structured via selective contracts pursuant to Section 140a SGB V, in addition to using the Prevention Act in the narrower sense (see Section 20a (2) SGB V). Selective contracts are special care contracts for cross-sectoral or interdisciplinary care as well as special care contracts involving service providers or their associations (Section 140a (1) sentence 2 SGB V). Visiting services and group activities do not involve interdisciplinary medical care, and the districts and cities responsible for assistance for the elderly are not service providers under health insurance law. However, the path to selective contracting may be opened by the variant of cross-sectoral care. The law does not define what a "service sector" is; it is also unclear whether "primary prevention" constitutes such a service sector [117]. According to the view expressed here, "prevention" as a whole is not a service sector but itself contains several service sectors.

Primary prevention is not limited to a specific provider of services or a specific type of services. It is therefore not on the same level as care elements (recognized as service sectors) such as "outpatient care", "provision of remedies" or "provision of aids" [118], but on the level above them, mirroring curative health care. Primary prevention involves averting and reducing the risk of disease (compare Section 20 (1) sentence 1 SGB V), while curative health care involves the treatment of manifested diseases (compare Section 11 (1) no. 4 SGB V versus Section 11 (1) no. 2 SGB V). In the same way that curative health care is offered in several service sectors, prevention may be offered in multiple ways, for example – as here – through visiting services on the one hand and group activities on the other, by districts and cities on the one hand and by nonstatutory welfare associations on the other. Prevention therefore does not constitute a service sector but, like curative health care, is implemented through the collaboration of the service sectors belonging to it.

According to the opinion expressed here, a selective contract within the meaning of Section 140a SGB V is also permissible for the purpose of coordinating and providing various preventive services, as is conceivable for more intensive interlinking of health care with the bodies responsible for assistance for the elderly. The health insurance funds may enter into corresponding contracts with districts, cities, and other providers of assistance for the elderly (Section 140a (3) sentence 1 no. 3a SGB V, Sections 12 sentence 1, 28 (2) SGB I). In this way, existing resources and processes of nonstatutory welfare associations, which the bodies responsible for social welfare may use cooperatively to fulfil their tasks, may also be activated indirectly (compare Section 5 (2), (3) and (5) SGB XII).

For the practical implementation of such agreements, it is therefore not necessary to come to a decision here regarding the question of whether and to what extent nonstatutory welfare associations can themselves be suitable contracting parties to a selective agreement as so-called "management companies" under Section 140a (3) sentence 1 no. 2 SGB V or whether this is precluded by the regulatory framework of Section 140a (3) SGB V vis-à-vis Section 5 (1) SGB XII.

For an even stronger interlinking of the funding bodies for combating social isolation in the elderly, the long-term care insurance funds and long-term care facilities (Section 140a (3) sentence 1 no. 3 SGB V) may also be included in the contract, provided that the insured persons covered by the selective contract are also in need of long-term care and thus fall under the scope of the long-term care insurance funds – which is not old people.

This type of intensive interconnection of the funding bodies via prevention-related selective contracts would purposefully further develop the legal concept of assistance for the elderly. Even under current law, the benefits of assistance for the elderly must be interlinked with the other benefits of social assistance and "the benefits of local assistance for the elderly and the municipal infrastructure to prevent and reduce the need for long-term care" (Section 71 (5) sentence 1 SGB XII). To reduce the need for long-term care, it also helps to reduce the risk of illness one step in advance. The need for long-term care is characterized precisely by permanently manifested, health-related impairments of independence and individual abilities (see Section 14 (1) sentence 3 SGB XI). The prevention of (mental) illnesses due to social isolation can therefore simultaneously contribute to preventing the need for long-term care [1].

Care and case management in the statutory health insurance system

Another potential concept which – among other things – contributes to the social integration of older people into public care structures is care and case management. It ensures access to health care services for those affected and thus also reduces (health-related) barriers which increase the risk of social isolation in the elderly. Care and case management is cross-sectoral

and involves both medical and non-medical service providers. Care and case management is always designed for a longer period of time and intervenes with regular visits to the affected person, especially regarding topics which are not part of medical care. This includes informing affected people about exercise programmes and organizing their participation therein, providing information on volunteer networks, supporting applications for low-threshold care and respite services, or providing interventions to improve the living environment (both as per SGB XI) and low-threshold support services. In geriatric care in particular, care and case management can bring about a shift from formal care to management of the daily routine [119]. In the RubiN project [120], more than half of affected people did not have a certified long-term care grade. To date, care and case management is included in the benefits catalogue of statutory health insurance only in exceptional cases, for example as discharge management in accordance with Section 39 (1a) SGB V, as part of specialized outpatient palliative care in accordance with Section 37b SGB V, or in care services in accordance with Section 71 (1a) SGB V. All of them, however, take up social isolation only reflexively.

An entitlement to care and case management in standard care would contribute to the reduction of social isolation in the elderly, at least for patients who meet the inclusion criteria for care and case management from the point of view of health insurance law, by improving the use of existing offers of assistance from all service areas of social law.

Legal entitlement in assistance for the elderly

As has been shown, the law on assistance for the elderly already offers a broad portfolio of services, some of which were evaluated favourably in the studies included in the benefit assessment. However, there is currently no particular, enforceable legal entitlement to specific services, e.g. the visiting services or group activities examined herein; the form of entitlement to assistance for the elderly is ultimately dependent on the will and finances of the local social welfare agencies. Moreover, the entitlement in question is only a "should" entitlement, not a "must" entitlement. From a jurisprudential point of view, it would therefore be desirable to put in place a legal entitlement as a subjective public right to concrete services to prevent and combat social isolation in the elderly. From a health services point of view, it should be noted that those in need of help require and demand low-threshold services, as confirmed again by the stakeholder workshops. Any court proceedings would represent too high a hurdle for people with impending or existing social isolation, and, in view of proceedings before the social courts typically taking several years, any proceedings would not be decided in time to affect these people’s care. Possible proceedings for interim relief might fail due to the prohibition of anticipation of the main action [121], especially with regard to the utilization of alternative offers.

However, the mere possibility of a legal position being enforced may contribute to improving the substantive position (this is shown, e.g. by freedom of information laws).

In view of the heterogeneity of the benefits in question, this concrete legal entitlement would not necessarily need to be mapped completely at the level of parliamentary law, i.e. in SGB XII. Another feasible option seems to be to implement a law concretization concept as presumed by the Federal Social Court in health insurance law (SGB V): Only very rudimentary rules have been established in benefit law, while countless regulations, agreements, etc. exist in service provision law; therefore, courts have presumed for some time that benefit law now constitutes only a subjective public legal framework, essentially a claim [122]. They deem the concrete claim to be concretized only on the basis of the provisions of the service provision law [123]. The service provision law thus takes precedence over benefit law [124,125].

In assistance for the elderly, a corresponding service provision law might also be developed from the agreements of the bodies responsible for assistance for the elderly with the local service providers, for example facility providers (see Section 71 (2) no. 5 SGB XII). However, it is beyond the scope of this report to do more than outline this idea. Developing a concept for concretizing the law with respect to assistance for the elderly would require even more in-depth considerations.

7 Synthesis of results

This HTA investigates the question whether effective measures exist to prevent and reduce social isolation and loneliness. For this purpose, randomized controlled trials were reviewed and evaluated, and health economic, ethical, social, organizational, and legal aspects were analysed on the basis of current literature. In view of the international consensus regarding the importance of social isolation and loneliness in the elderly [126], few randomized controlled trials evaluating the benefits of interventions can be found.

7.1 Summary of benefit assessment

The benefit assessment is based on a total of 14 randomized controlled trials which were identified from 18 publications, 6 of which reporting on the evaluation of preventive interventions and 8 reporting on the evaluation of more therapeutic interventions. In both groups, some programmes were implemented by volunteers, while others were implemented by professionals in the health and social care sector. However, the initiative for the volunteer-based programmes always came from a university institute or a social welfare institution which also trained the volunteers or provided support.

The implemented interventions are highly heterogeneous in nature and can be roughly categorized into groups. Three studies investigated the effectiveness of volunteer visits to the private homes of the elderly (participants). These studies all belonged to the group of treatment studies, i.e. the target group addressed by these studies are older people with pre-existing social isolation and/or loneliness (Conwell 2020, MacIntyre 1999, Onrust 2008 / 2010).

Support provided through phone calls with volunteers has been evaluated in 2 studies, by Heller 1991 with a therapeutic approach and by Hind 2014 / Mountain 2014 with a preventive approach.

The prevention-oriented interventions by Chan 2017 (Tai Chi Qigong intervention combined with a neighbourhood health guide) and the technical tutorial on tablet computers implemented by Fields 2020 for older people already affected by social isolation and loneliness were implemented at least in large part by volunteers.

Among the interventions implemented by professional health care providers and social workers, group services either with a preventive character (Ristolainen 2020, Saito 2012, Shvedko 2020, Zhang 2019) or with a therapeutic approach (Cohen-Mansfield 2018, Pynnönen 2018 and Routasalo 2009 / Pitkala 2009 / 2011) dominate. In this context, the contents of the implemented group programmes are also very heterogeneous and range from pure sports and exercise programmes (e.g. Shvedko 2020) and programmes with a focus on leisure activities

(Ristolainen 2020) to targeted, psychotherapy-oriented interventions to strengthen social skills (e.g. Cohen-Mansfield 2018, Zhang 2019).

The duration of interventions was also very heterogeneous, ranging from 1.5 months (MacIntyre 1999) to 12 months (Conwell 2020). In most studies, the intervention duration was between 3 and 7 months. In 6 of the 14 studies, effects were measured immediately after the end of the study, i.e., there was no follow-up. Six studies reported results after follow-up durations of 1.5 to 12 months, while 1 study (Routasalo 2009 / Pitkala 2009 / 2011) reported results after 3, 12, and 24 months. Onrust 2008 / 2010, on the other hand, did not report an exact length of the intervention, but conducted surveys 6 and 12 months after baseline.

Most studies used CAU without intervention as the comparator intervention. In 4 studies, CAU was combined with a waiting-group approach, and only 1 study (Onrust 2008 / 2010) supplemented CAU with a minimal intervention (brochure on the topic of grieving).

The studies also differed in their recruitment of participants. In some studies, participants were hand-picked for the study by social workers or caregivers (e.g. Chan 2017, MacIntyre 1999). Others chose to publicize the study through multiple avenues, e.g. media, bulletin boards, or practice flyers. Those interested in participating then made contact on their own initiative (Hind 2014 / Mountain 2014, Ristolainen 2020, Shvedko 2020, Conwell 2020). In the vast majority of studies, a sample was drawn from an existing dataset (e.g. registers or practice lists), and potential study participants were contacted by the study team (Saito 2012, Zhang 2019, Heller 1991, Fields 2020, Onrust 2008 / 2010, Pynnönen 2018, Routasalo 2009 / Pitkala 2009 / 2011).

The studies can be broadly divided into 4 groups according to the number of participants: the pilot studies by Shvedko 2020 and MacIntyre 1999 worked with fewer than 50 participants; between 50 and 100 participants are found in Hind 2014 / Mountain 2014, Saito 2012, Fields 2020, and Cohen-Mansfield 2018. Ristolainen 2020 and Onrust 2008 / 2010 included between 100 and 200 participants, and 4 of the treatment studies (Conwell 2020, Heller 1991, Pynnönen 2018, and Routasalo 2009 / Pitkala 2009 / 2011) had over 200 participants.

In the majority of studies, the mean age of the study population was between 70 and 80 years. In Shvedko 2020 (intervention for increasing physical activity) and Onrust 2008 / 2010 (widow-to-widow programme, volunteer support), participants are somewhat younger, averaging between 60 and 70 years of age. In contrast, the study population in Zhang 2019 tends to be older, with a relevant proportion being over 80 years old.

In 1 study, the proportion of male participants was higher than the proportion of female participants (Zhang 2019), in 3 studies the proportions of men to women were roughly

balanced (Shvedko 2020, Conwell 2020, Fields 2020), and all remaining studies had more female than male participants.

A total of 11 studies (4 of 6 prevention studies and 7 of 8 treatment studies) excluded study participants with cognitive impairment.

Vulnerability to social isolation and loneliness was determined by different characteristics in the prevention studies: Zhang 2019 and Hind 2014 / Mountain 2014 used advanced age alone as an indicator of vulnerability to social isolation and loneliness, Chan 2017 employed lack of social contacts, Ristolainen 2020 used living alone and utilization of health and social services, and Saito 2012 employed change of residence combined with advanced age. Only Shvedko 2020 screen systematically for vulnerability to social isolation and loneliness in the pilot study. In 6 of 8 studies with a therapeutic research question, social isolation and loneliness were systematically surveyed as inclusion criteria, while 2 studies relied on their assessment by study personnel (Fields 2020 and MacIntyre 1999).

Risk of bias

The risk of bias across outcomes was rated as high in all studies. Due to the nature of the intervention, none of the studies was able to implement the blinding of treatment providers and participants. In Hind 2014 / Mountain 2014, the risk of bias was rated as low for all other reviewed risk factors. All remaining studies exhibit at least 1 unclear or unmet criterion in addition to lack of blinding. Notably, it was impossible to assess reporting bias. For 10 of the 14 studies, no protocol or registry entry was available, and for 3 others, there were discrepancies between the study report and the protocol or registry entry. Only for Hind 2014 / Mountain 2014 and Shvedko 2020 was it possible to rule out reporting bias.

Zhang 2019 reported a drop-out rate of 18% in the intervention group and 5% in the control group. In the Conwell 2020 study, it was impossible to implement the originally planned outcome surveys at 24 months due to difficulties with volunteer recruitment. For the 12-month survey point, approximately 15% of participants had to be censored in both groups, as the study had to be terminated due to lack of funding. Difficulties with volunteer recruitment led to early study termination in Hind 2014 / Mountain 2014. Out of the 248 originally planned participants, 157 were in fact recruited and randomized. For 50 out of 78 participants randomized to the intervention group, no volunteers were available for the telephone intervention; therefore, the study was terminated, and results were ultimately based on 56 participants (N = 26 for the intervention group and N = 30 for the control group).

Outcomes

The studies reported results on all outcomes specified in the reporting protocol except for adverse events, which were not examined in any study.

Among the prevention studies, 5 of 6 studies reported results on the outcome of loneliness, 4 of 6 studies on outcomes on social participation, and 3 of 6 studies each on outcomes on health-related quality of life, psychological resources, and depression. The remaining morbidity outcomes and psychological resources are addressed sporadically.

In the treatment studies, social participation parameters (5 of 8 studies) and loneliness (5 of 8 studies) are likewise the most frequently reported outcomes, followed by psychological resources outcomes (4 of 8 studies) and depression (4 of 8 studies). All other outcomes were found only sporadically, each in no more than 2 of 8 studies.

The number of surveyed outcomes ranges from 1 (Zhang 2019, Cohen-Mansfield 2018) to 16 (Hind 2014 / Mountain 2014).

The comparison of results across studies is further complicated by the use of different survey tools. For example, in the 7 studies reporting results on the depression outcome, the PHQ-9, the GDS, and the CES-D are each used twice. One study used the HADS. Clearly defined primary outcomes were defined in only 1 prevention study (Hind 2014 / Mountain 2014) and 3 treatment studies (Cohen-Mansfield 2018, Conwell 2020, and Pynnönen 2018), with only Hind 2014 / Mountain 2014 planning a sample size based on the primary outcome and reaching only 20% of said sample size.

Results by outcomes

The prevention studies reported statistically significant effects in favour of the intervention for a total of 8 outcomes: mental health, physical role functioning, bodily pain, loneliness, social support, familiarity with services for the elderly, social functioning, and life satisfaction. For 3 other outcomes assessed in the prevention studies, namely social support, trust or mistrust in persons, and institutional trust, at least subscales of an instrument show a statistically significant effect in favour of the intervention.

After taking into account the risk of bias and formally examining the relevance of the described between-group differences (effect sizes, Hedges' g method), a hint of benefit from a specific intervention can be derived only for the outcome of social support, based on 1 study.

The included treatment studies report statistically significant effects in favour of the intervention for a total of 9 outcomes: mortality, anxiety, self-reported health status, cognitive performance, health-related quality of life, loneliness, life satisfaction, well-being, and perceived burdensomeness. Only for the outcome of social cohesion were statistically significant effects in favour of the intervention reported in at least 1 subscale of another instrument.

After formal testing of between-group differences for relevance (effect sizes, Hedges' g method) and taking into account risk of bias, a hint of benefit of selected interventions can be derived for the outcomes of mortality, anxiety, self-reported health status, and life satisfaction. These hints are likewise based on only 1 study each.

Results by intervention

The interventions conducted in the 14 included studies can be roughly divided into 5 groups:

- visits by volunteers in the patient's private home (Conwell 2020, MacIntyre 1999, Onrust 2008 / 2010)
- telephone conversations with volunteers (Heller 1991, Hind 2014 / Mountain 2014)
- professional-led groups (Cohen-Mansfield 2018, Pynnönen 2018, Routasalo 2009 / Pitkala 2009 / 2011, Ristolainen 2020, Saito 2012, Shvedko 2020, and Zhang 2019)
- computer tutorials for lonely people conducted by volunteers (Fields 2020)
- Tai Chi Qigong intervention supported by a volunteer health guide (Chan 2017)

However, heterogeneity within the groups is too high for summary statements on effectiveness to be meaningful.

Hints of benefit for the intervention regarding individual outcomes were derived only for visits by volunteers in participants' private homes (2 of 3 studies) and professional-led groups (2 of 7 studies).

For a programme with friendly visits, Conwell 2020 report statistically significant between-group differences for the outcomes of anxiety and perceived burdensomeness. No differences were found for suicidality (the study's primary outcome), depression, or sense of belonging. After formal testing for relevance, it was possible to derive a hint of benefit only for the outcome of anxiety.

MacIntyre 1999 implemented a visiting programme with gerontology students and reported differences in favour of the intervention group regarding life satisfaction. No differences were found for self-reported health status or social support. Relevance was shown for the outcome of life satisfaction, and thus a hint of benefit for this outcome was derived.

The professional-led programme investigated by Zhang 2019 aims to gradually build social skills through self-reflection and communication with others. Conversations are initially held individually (every 2 weeks), followed by small groups (2 to 3 participants), and finally monthly in larger groups (7 to 10 participants). For social support, which was the only surveyed outcome, statistically significant and relevant differences were reported in favour of the intervention group. This results in a hint of benefit of the intervention.

Another professional group intervention was implemented by Routasalo 2009 / Pitkala 2009 / 2011. Within the framework of psychosocial group rehabilitation, fixed groups conducted weekly meetings with the aim of promoting social integration and peer support. Intervention-group participants were invited to choose between 3 groups: therapeutic writing and psychotherapy, sports/exercise, and arts or stimulating activities. Overall, the effectiveness of the intervention was assessed using 7 outcomes. Statistically significant improvements were reported for mortality, self-reported health status, cognitive performance, health-related quality of life, and well-being. No differences were described for the outcomes of loneliness and social support. Relevance was shown for the outcomes of mortality and self-reported health status, and thus a hint of benefit of the intervention was derived for these outcomes.

7.2 Summary of health economic assessment

The health economic assessment investigates, on the one hand, the costs associated with the technology (intervention cost). On the other, it analyses health economic studies which draw conclusions on cost effectiveness of the technology versus the comparator intervention. In addition, comparative health economic studies drawing conclusions on the costs of the intervention and comparative intervention can be taken into account.

On the basis of the information provided in the publications, the potential intervention costs for the German context were determined. For the visiting service by volunteers (widow-to-widow programme by Onrust 2008/2010), they equalled €246 to €403 per participant, depending on whether supervision was involved. For the professional-led group intervention (psychosocial group rehabilitation by Routasalo 2009 / Pitkala 2009 / 2011), intervention costs were found to average €434 per participant.

For the evaluation of the health economic dimension, 2 studies were identified and included. These are a cost–utility analysis and a cost–cost analysis. The studies compare 2 different interventions aimed to prevent and reduce social isolation and loneliness in the elderly. They are a volunteer visiting service and a professional-led group intervention. Both studies compared the interventions versus CAU, with Onrust 2008 / 2010 additionally sending information brochures. In Onrust 2008 / 2010, there were no statistically significant differences with respect to either the cost difference (€210 per person; $p = 0.563$) or the benefit difference (0.01; -0.02) per person and per year. The incremental cost-effectiveness ratio (ICER), which was nevertheless determined, was reported as €6827 per QALY gained.

In the Routasalo 2009 / Pitkala 2009 / 2010 cost-cost analysis, a statistically significant difference in mortality was reported in favour of the intervention group. The hazard ratio was 0.039; 95% CI: [0.15; 0.98]; $p = 0.044$. The intervention group exhibits statistically significantly higher costs with a cost difference of -943€ per person per year; 95% CI: [-1955; -127]; $p = 0.039$. The cost difference exceeds the intervention cost of 881€ per person.

7.3 Summary of ethical, social, legal, and organizational aspects

The investigation of the ethical, social, organizational, and legal domains revealed a wealth of reciprocal interactions between the different interventions on the one hand and the specific social environments regarding social norms and values, patient preferences, resource distribution in a society, and access to the interventions on the other.

Ethical aspects

The basis for the analysis of the ethical aspects was the public health ethics framework [56], in alignment with Hofmann's questionnaire [57].

On the basis of the identified ethical aspects, 7 ethical assessment criteria were developed. The identification of ethical aspects was based on the analysis of 11 professional articles as well as the content of 2 interviews with people affected by social isolation and loneliness and the content of 1 interview with a volunteer working in assistance for the elderly. After a stakeholder workshop with professionals (stakeholders) from assistance for the elderly, 5 criteria were assessed as "highly relevant" in the German care context.

The assessment criterion "introduction and sustainability of interventions" particularly addresses the need for interventions to be planned for the long term and financed accordingly because the target group might be overwhelmed if services and projects were to constantly change. The criterion "needs assessment and the silent elderly" focuses on the fact that planned interventions or those who implement them must make an effort to actually reach socially isolated and lonely people. With this target group of isolated and lonely elderly people, there is a particular risk of them being "overlooked" and not reached by the interventions. The evaluation criterion "raising awareness of offered services" is a related one. This criterion highlights the fact that those affected by social isolation and loneliness are difficult to reach and that advertising efforts would therefore need to be highly differentiated. The criterion of “user-oriented services” demands closely matching interventions’ contents to local needs to ensure that they are perceived as attractive. The criterion of “consideration of causes” serves as a reminder that interventions must also address the causes of social isolation and loneliness in order for them to be effective in the long term.

Social and organizational aspects

Social and organizational aspects were analysed using the conceptual framework developed by Mozygemba 2016 [58]. Relevant contents were extracted from 9 publications (found in the scoping search), from 2 interviews with people affected by social isolation and loneliness, from 1 interview with a volunteer from assistance for the elderly, and from the discussion of ethical, social, legal, and organizational aspects with professionals working in the social assistance system conducted in a stakeholder workshop. In addition, social and/or organizational aspects

were extracted at varying frequency and explicitness from all 14 studies included in the benefit assessment (focusing on the discussion sections of the respective publications).

The opportunity to establish contacts in order to enable communication among affected people is particularly crucial for the image and understanding of interventions as well as for maximizing the usefulness perceived by affected people. Group meetings are deemed to be the most effective way to create this opportunity, optimally with active elements such as excursions, games, singing and eating together. For the interventions' target group, the focus is primarily on direct contact and communication as well as direct experiences. The interventions must be "fun" and take place in a safe environment. From the user and provider perspective, health-related outcomes are only a secondary priority in terms of the usefulness of interventions.

Interventions tackling social isolation and loneliness in the elderly are particularly well accepted and deemed suitable if they are locally adapted and the target group can help design them. Participants want to experience a balanced give and take so that they feel like their autonomy is preserved rather than being in a dependent relationship. Ideally, interventions are developed in a participatory manner with those affected locally and evaluated on an ongoing basis. In this way, affected people can experience themselves as stakeholders, services are adapted to the local context as well as to individual needs, and participants can perceive the atmosphere as predominantly natural.

It should be emphasized that, based on the entirety of elderly people, only very few actually utilize the services offered by assistance organizations for the elderly. The reasons for this include the fact that services are perceived as unattractive or unsuitable, that there are psychological hurdles, and that those affected do not receive information about interventions due to their social isolation and loneliness. People who have led active lives in the past are more likely to be reached, while more passive people remain difficult to reach. There is a risk of interventions tackling social isolation and loneliness first reaching those who exhibit the least need.

It is essential to take into account the regionally very diverse sociocultural aspects of the target group, and culturally sensitive services which also take into account the socioeconomic framework conditions are needed. Social inequalities in utilization must be countered by making the services as low-threshold and outreach-based as possible and placing a special focus on minorities and vulnerable groups. Services must be specifically advertised at interfaces such as doctors' offices or pharmacies, where most older persons have a point of contact. Cost sharing by affected people must be compensated in a socially acceptable way, and affordable transport options must be available.

In organizational terms, all the interventions identified in the included studies can also be enshrined in Germany, and in some cases, they already are in a variety of ways. Points of reference can be found above all in SGB XII under assistance for the elderly. In Germany, this legal norm covers a wide range of bodies responsible for assistance for the elderly, counselling centres for the elderly, and social welfare centres. Professionals in the field of assistance for the elderly see this diversification of services as a decisive factor in reaching the target group. At the same time, this diversification is associated with a regionally very heterogeneous availability of interventions tackling social isolation and loneliness in the elderly, a large urban-rural divide as well as unsystematic quality management.

Using a mix of professionals and volunteers seems promising when it comes to the staffing of the interventions. Local volunteers who are themselves affected by social isolation and loneliness can ensure a target group-oriented and low-threshold intervention at eye level, while the professionals can also focus on the aspects of empowerment, autonomy, and sustainability. However, the cooperation between volunteers and professionals requires generous resources for training, further education, intravision, and, if necessary, supervision.

Legal aspects

The investigation of legal aspects on the basis of the information sources from the Juris database as well as further legal texts, regulations, and guidelines demonstrated that social isolation and loneliness in the elderly are not a life risk represented by health insurance law. Current health insurance law provides for the prevention and combating of social isolation and loneliness in the elderly reflexively, but not as a main purpose. In contrast, social welfare in the form of assistance for the elderly already includes a wide variety of measures to combat social isolation and loneliness in the elderly, including volunteer visiting services and professionally supervised group activities. Health insurance funds may also take preventive action since social isolation and loneliness in the elderly often increase the risk of mental illness.

Under the law governing long-term care insurance, even acute social isolation and loneliness in the elderly cannot, by itself, justify a claim for AUA benefits. In the view of the authors of this HTA, current law already allows health insurance funds to conclude selective contracts with long-term care insurance funds, local authorities, and welfare institutions in accordance with Section 140a SGB V which also address the better integrated prevention of social isolation and loneliness in the elderly.

De lege ferenda, care and case management might also conceivably become an integral part of standard care under health insurance law. For the law on assistance for the elderly, it is further conceivable to establish a subjective public right to assistance in the event of social isolation and loneliness in the elderly in order to provide those affected with enforceable legal positions even beyond the existing services; to this end, the law on assistance for the elderly

might be restructured to include a benefits catalogue of favourably evaluated interventions. This could be modelled after health insurance law, which has implemented the very heterogeneous benefit prerequisites and benefit contents in a detailed and subjective legal manner in its concept for concretizing entitlement.

Cross-domain discussion

The discussion of ethical, social, organizational, and legal aspects of interventions tackling social isolation and loneliness demonstrated that social isolation and loneliness do not have any disease value in themselves but are perceived primarily as a social phenomenon and problem. Lack of participation is consistently associated with health limitations which increase morbidity and mortality. From a social, organizational, ethical, and legal perspective, this results in unclear responsibilities, which complicates the structural integration of interventions at all levels.

In Germany, interventions tackling social isolation and loneliness in the elderly are organized and offered mainly by nonstatutory social welfare organizations using a mix of volunteers and employees. In the stakeholder workshop, the professionals from the social assistance system emphasized that all of the identified interventions could conceivably be implemented or are already being implemented in German structures through SGB V, IX, XI and XII. Social isolation and loneliness have both medical and social impacts, which is why health and social systems should cooperate [66]. Particularly the professionals point out that the distinction between preventive and therapeutic interventions is not relevant in practice. From a legal perspective, however, the distinction provides a basis for health insurance funds to cooperate more closely with long-term care insurance funds, municipalities, and welfare institutions, e.g. in selective contracts pursuant to Section 140a SGB V. Social isolation and loneliness are stigmatized, and the search for support is made more difficult, for instance, by the welfare office being associated with negative connotations. Regarding the law on assistance for the elderly, the discussion therefore focuses on establishing a subjective public right to assistance in cases of social isolation and loneliness in the elderly in order to provide those affected with enforceable legal positions even beyond the existing services. Those affected do not like to see themselves in the role of aid recipients [87]. Interventions should therefore involve a reciprocal design so that those affected can get involved and feel that they are providing assistance [60,66,71]. At the same time, the blurring of the boundary between affected people and those helping enables low-threshold interaction at eye level, even for people with very low self-esteem and contact with the outside world [60,63,66,69-71,87].

From ethical, social, and organizational perspectives, the introduction and sustainability of interventions tackling social isolation and loneliness are particularly relevant. Professionals, volunteers, and those affected emphasize the need for sustainable and regular services. Social isolation and loneliness require continuous efforts, which are not available in short-lived

project structures as were examined in the intervention studies. Interventions which target the social environment and teach participants specific social skills to build networks might be effective even in a limited format [72]. However, the included studies were only partially able to substantiate this [44,59,64,67]. Intervention studies focus primarily on health-related outcomes. Affected people and stakeholders, on the other hand, attach particular importance to the interventions' process quality [66,74-76]. They primarily desire the initiation of new contacts and an enjoyable time in company. From social, organizational, and ethical points of view, interventions must be designed in a low-threshold, local, target-group-specific, and participatory manner in order to achieve this goal. Affected people, stakeholders, and study authors deemed active group interventions to be the most effective. However, it is challenging to place people affected by social isolation and loneliness into a group programme. The ethical criterion "consideration of causes" for social isolation and loneliness was generally given little attention [60,65,72,73,89]. In the reviewed studies, the investigated interventions tackling social isolation and loneliness rarely included an analysis of personal psychological barriers or specifically addressed self-efficacy [72]. Current services should focus more on the young-at-heart elderly and rework their "stale" image. The ethical assessment criterion "needs assessment and the silent elderly" established in this HTA is directly tied to these social and organizational aspects. From an ethical and social point of view, services must be more target-group oriented. Cultural diversity must be taken into account in the offered interventions in order to reflect societal realities [43,87]. The diversity of services differs widely in different locations. Currently, many of the investigated interventions did not even address affected men [43,66,72,85,91].

A potentially unfavourable aspect is that interventions tackling social isolation and loneliness in the elderly mainly reach those who are already active and have been so for most of their lives. Passive persons who have been affected by social isolation and loneliness for many years and have little self-confidence are often impossible to reach [60,62,64,72,87]. Also, few interventions existed for severely impaired and particularly vulnerable persons [63,68,74-76], or this group had to drop out of the utilized interventions [67,72,73]. Only in isolated cases have particularly disadvantaged groups been shown to benefit [70,71]. At the same time, registry-based recruitment strategies [63,70,71] showed that persons who do not exhibit some level of suffering either do not participate or prematurely drop out of interventions. These aspects were also taken into account in the ethical assessment criterion "raising awareness of offered services". People with poor quality of life and limited ability to articulate themselves well are very difficult to reach [62,87], and corresponding efforts must therefore be intensified.

7.4 Logical model

The logical model in Figure 2 presents the main aspects on the individual domains and their interrelationships.

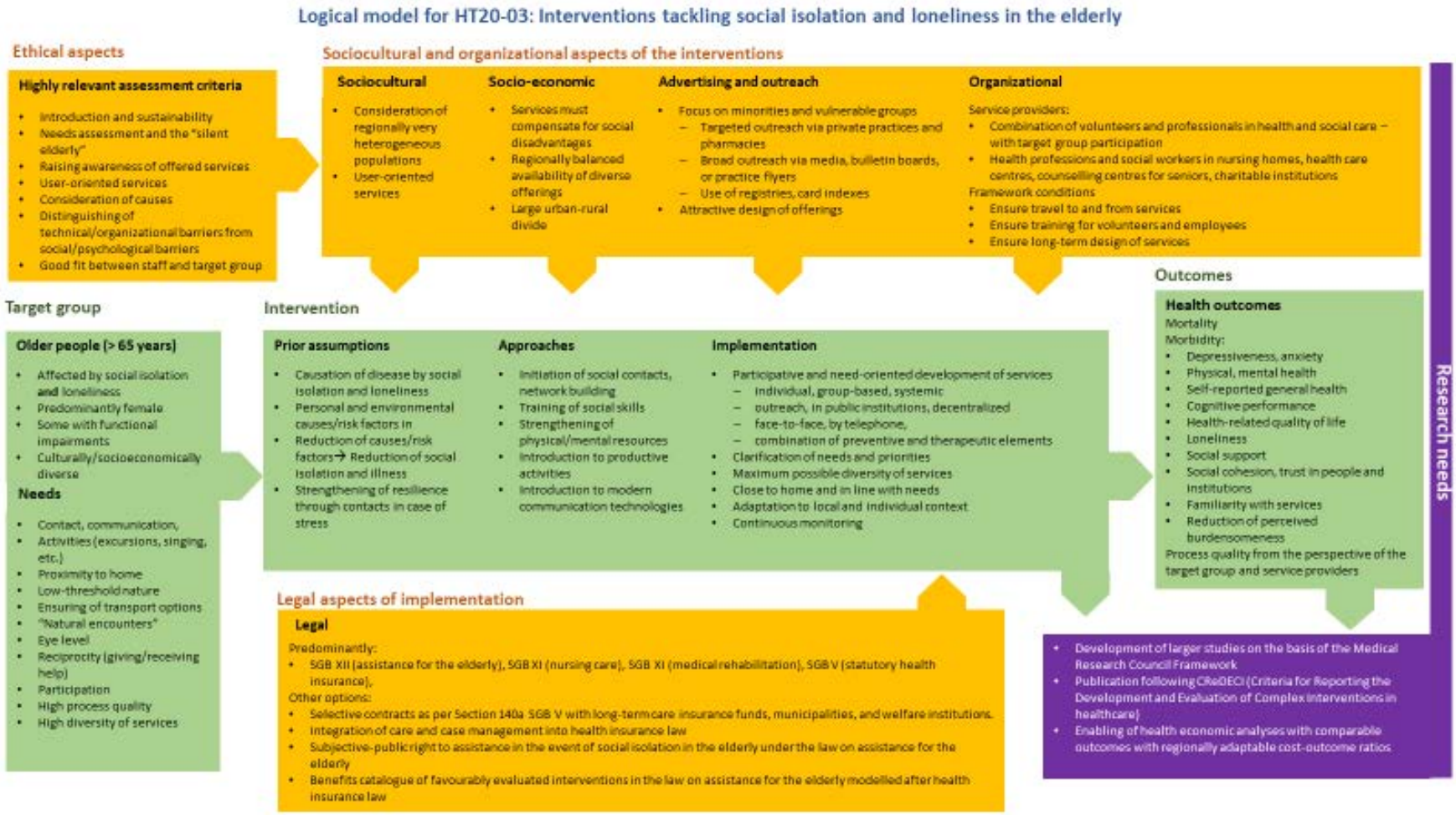

Figure 2: Logical model for HT20-03: interventions tackling social isolation and loneliness in the elderly

8 Discussion

In summary, it is difficult to draw general conclusions regarding the effectiveness of the interventions examined in the studies on the basis of the reviewed study pool. This is due to both methodological and content-related aspects.

From a methodological point of view, it should be noted that all studies have a high risk of bias, which makes them susceptible to systematically overestimated or underestimated effects. In addition, particularly indifferent results are of questionable informative value because only 3 studies involved a prospective sample size estimation. Onrust 2008 / 2010 planned their sample size to demonstrate moderate effects and reached this sample size. Ristolainen 2020 based their sample-size planning on studies with similar interventions in similar populations and reached the sample size. Hind 2014 / Mountain 2014 planned sample size based on their defined primary outcome and reached only 20% of their target sample size. Five studies justified their sample size either based on the potential participants who are reachable from a limited sample or based on the intervention's capacity (Fields 2020, Routasalo 2009 / Pitkala 2009 / 2011, Pynnönen 2018, Saito 2012, Zhang 2019). Three studies characterized themselves as pilot studies (Chan 2017, MacIntyre 1999, Shvedko 2020), and 3 studies did not provide any information on the rationale for the sample size (Conwell 2020, Cohen-Mansfield 2018, Heller 1991).

It should be noted that, among both the prevention studies and the treatment studies, one-third are "negative" studies, i.e. studies with no statistically significant effects in favour of the intervention group on any of the outcomes examined. The preventive interventions comprise a professional-led group programme from the United Kingdom with physical exercise followed by workshops (Shvedko 2020). This is a feasibility study conducted in preparation for a confirmatory randomized controlled trial which was not designed to survey efficacy.

Among the treatment studies, Fields 2020, whose intervention consisted of technology training on tablet computers, reported no differences between intervention and control groups with regard to the target group-relevant outcomes defined in the context of the HTA. Advantages in favour of the intervention group, however, were reported with respect to technology use and confidence in technical skills. Heller 1991 also reported no between-group differences for their intervention on establishing telephone friendships among elderly, lonely women of low socioeconomic status. The main reasons for the negative results are thought to be a strong Hawthorne effect (control group experiencing favourable effects as a result of study participation alone) and an improper fit of the intervention (lack of family support as the main problem of the target group). Onrust 2008 / 2010, who found no between-group differences for the intervention group and the control group with minimal intervention (information folder), discuss methodological problems (e.g. selection errors, low response

rate, variable adherence, lack of monitoring), but also an incorrect fit of the intervention to the target group to explain the lack of effects.

Only 1 study in the entire study pool, the therapeutically focused Cohen-Mansfield 2018 study, reported statistically significant differences in favour of the intervention group, both immediately after the 6-month intervention and after a follow-up of an additional 3 months – using only a composite outcome for loneliness. The multistage, professional-led group programme achieved an effect size of 0.29, which the authors classify as moderate. The authors assume that the effect was no more than moderate due to the intervention's short duration, which was also lamented by the study participants, and the lack of available community services which would have allowed practising the newly acquired social skills after the end of the intervention. Zhang 2019, another study using a preventive approach and examining only 1 outcome reported statistically significant results for the outcome of social support, although immediately after the 7-month intervention. The effect size of 0.64 can be classified as moderate. Thus, the sustainability of the benefit cannot be determined.

Routasalo 2009 / Pitkala 2009 / 2011 report statistically significant differences in favour of the intervention group with regard to mortality and morbidity outcomes, but not for loneliness and social support for their group rehabilitation programme focused on psychosocial support for lonely elderly people. The authors attribute this finding to the survey instruments used for the volatile outcomes of loneliness and social support lacking sensitivity to change.

All other studies report isolated significant differences in favour of the intervention groups, without a distinguishable consistent link to specific intervention types, therapeutic indications (preventive or therapeutic), or outcome categories.

Due to the methodological problems outlined above, the validity of these results is difficult to assess.

8.1 Reporting quality of the evaluation studies on complex interventions

From a substantive perspective, a factor making it difficult to interpret results is that the examined interventions are all complex interventions which (a) typically consist of multiple interacting components, (b) are impacted by the behaviour of both intervention providers and participants, (c) take place at different organizational levels, (d) address multiple different outcomes, and (e) are adaptable to some degree to different needs [127]. Measuring and interpreting effects of complex interventions which can be influenced by a variety of internal as well as contextual factors is challenging. In 2008, the Medical Research Council (MRC) in the United Kingdom (most recently) proposed a methodological framework for the development and evaluation of complex interventions, which essentially comprises the steps of literature review, theory development, process and outcome modelling, feasibility testing, and outcome and process evaluation. At the same time, the framework calls for the

transparent documentation of all steps – not least for decision makers who have to interpret the results of evaluation studies and implement them against the background of uncertain evidence [127]. In 2015, the 13-item CReDECI 2 checklist was developed as a reporting guideline for complex interventions to facilitate the required transparency and indirectly to encourage the implementation of the required steps. Four of the 13 items relate to intervention development, 1 to piloting, and 8 to evaluation [128]. This list of criteria can also be used to assess the reporting quality (and indirectly the methodological quality) of evaluation studies of complex interventions. For the post-hoc review of the studies included in the HTA, 1 item on evaluation development (underlying theoretical basis, criterion 1, see Table 14) as well as the 8 items on evaluation were used (see key in Table 14). The basis for the assessment were all available publications on the respective studies.

Table 14: Assessment of reporting quality for complex interventions (extract from CReDECI 2)

Study/criterion	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Prevention studies									
Chan 2017	+	(+)	-	(+)	(+)	+	(+)	-	-
Hind 2014 / Mountain 2014	+	(+)	+	+	+	+	+	+	+
Ristolainen 2020	+	(+)	-	-	-	-	-	-	-
Saito 2012	(+)	(+)	-	-	-	-	(+)	-	-
Shvedko 2020	+	(+)	(+)	+	+	(+)	+	-	-
Zhang 2019	+	(+)	-	-	-	-	-	-	-
Treatment studies									
Conwell 2020	+	(+)	+	-	-	-	-	-	-
Fields 2020	-	(+)	(+)	(+)	(+)	+	+	+	-
Heller 1991	+	+	+	-	-	-	(+)	-	-
MacIntyre 1999	-	(+)	+	-	+	-	-	-	-
Onrust 2008/2010	+	(+)	+	-	(+)	-	(+)	-	+
Cohen-Mansfield 2018	+	(+)	(+)	-	-	?	(+)	(+)	-
Pynnönen 2018	+	(+)	(+)	-	-	-	-	-	-
Routasalo 2009 / Pitkala 2009/ 2011	+	(+)	(+)	-	?	?	(+)	-	-

Criteria:
1: description of the intervention's underlying theoretical basis
2: description of the control condition and reasons for the selection
3: description of the strategy for delivering the implementation within the study context
4: description of all materials and tools
5: description of fidelity with the study protocol
6: description of the process evaluation (and its underlying theoretical basis)
7: description of internal facilitators/barriers on the basis of the process evaluation
8: description of external facilitators/barriers on the basis of the process evaluation
9: description of resources required

Study/criterion	1	2	3	4	5	6	7	8	9
Key: +: +: criterion met (+): criterion partially met -: criterion not met ?: publication not accessible									

The review shows that only the Hind 2014 / Mountain 2014 study, available as a 250-page study report, meets all the reporting quality requirements for evaluation studies of complex interventions. Chan 2017 and the more recently published Fields 2020 and Shvedko 2020 also at least partially meet a large proportion of the criteria. For these studies, it would be possible to determine to what extent their interventions might be adapted to a given German context or what modifications would be required, taking into account the aspects highlighted in Chapter 6 of this report. All other study reports exhibit major gaps in reporting quality. Criterion 2 "description of the control condition and reasons for the selection" was marked as "partially fulfilled" in all studies but one. The control condition was identified in all studies, but a rationale was provided only in Heller 1991. While the "description of the strategy for delivering the intervention within the study context" was provided in most publications, all reports except for the 4 studies mentioned above lack any descriptions of "materials and tools" used. Equally rarely is a "description of a process evaluation" provided, which would allow conclusions to be drawn about the feasibility of implementing the intervention. Criterion 7 "description of internal facilitators/barriers as revealed by the process evaluation" is partially met in most studies. Generally speaking, the authors of the studies mention some internal barriers or facilitators in the discussion section in order to support their own interpretation of the results. However, the aspects mentioned are not the result of a systematic process evaluation. "External facilitators or barriers" are reported much less frequently.

8.2 HTA report compared with other publications

This HTA investigates the question whether effective interventions exist to prevent and reduce social isolation and loneliness in elderly people living in their private homes. For this purpose, 14 randomized controlled trials were consulted and evaluated, and ethical, social, organizational, and legal aspects were considered on the basis of current literature. To prepare the report protocol, a focused search was conducted for systematic reviews on the research question, with 171 hits being identified on 9 December 2020. Of these, 22 reviews were reviewed in full text. None of the identified publications fully corresponded to the research question of the HTA. In most cases, there were discrepancies with regard to the inclusion criteria for study participants (living in their private homes, age 60 or 65 years or older). Further discrepancies involved restrictions to certain intervention methods (e.g. only

interventions from the spectrum of physical activity or focus on technical support systems), or methodological issues, e.g. the inclusion of non-randomized controlled study designs.

The rapid review by Veazie 2019 et al. [20] comes closest to the HTA's research question. Said review investigated the effectiveness of interventions aimed at reducing social isolation and loneliness in elderly people living in their private homes. The authors included 16 studies (7 RCTs, 8 pre-post comparisons, and 1 cross-sectional study with post-test survey; search period 2013 through 2018). The authors broadly grouped the interventions into 4 classes: interventions which increase physical activity, interventions which increase social cohesion and contact, interventions which address the viewing and/or creation of arts and culture, and interventions which facilitate access to the health care system or services thereof. Of 8 studies rated as being of moderate to good methodological quality (7 RCTs and 1 pre-post comparison), only 2 RCTs demonstrated effects on health outcomes (quality of life, depression, functionality), and only 1 of the 2 RCTs showed effects on social functioning levels (social capital). Based on its assessment/result, the Veazie 2019 working group concluded with regard to morbidity outcomes that interventions aiming to increase physical activity are the most promising for improving health in the elderly. However, they also point out the inconsistency of results and the fact that the results can be demonstrated only for a short period of time. The authors of the included studies were unable to reach a conclusion concerning outcomes on social functioning levels and social participation. However, they mention their results suggesting that interventions carried out by professionals are generally more successful.

In its report on social isolation and loneliness among older people (2021), the World Health Organization likewise points out that limited evidence is available on the effectiveness of interventions. The WHO argues that international scientific efforts must be strengthened to determine which intervention components are effective under which conditions. Like this HTA report, the WHO report on social isolation and loneliness among older people emphasizes that few randomized controlled trials have been conducted to date, the samples were often too small, and the interventions often did not reach the most lonely and vulnerable. To generate conclusive evidence, the WHO report – like the present HTA – calls for evaluation studies to be theory-based, comprehensive, and of high methodological quality [126].

Irrespective of the available evidence, the World Health Organization [126] furthermore calls for more global efforts to tackle social isolation in the elderly. It recommends 3 key intervention strategies:

- expanding interventions on the individual and interpersonal level, both face-to-face and digitally, such as through cognitive behaviour therapy, social skills training, and befriending

- improving strategies at the supra-individual level which address infrastructural aspects (e.g. transport, digital inclusion, built environment) and promoting age-friendly communities (e.g. flat-sharing communities for older people, intergenerational housing and leisure projects)
- pursuing strategies at the societal level, such as laws and policies to address, e.g. ageism, inequality, and the digital divide.

8.3 HTA report compared with guidelines

Social isolation and loneliness have no disease value in themselves. Therefore, no guidelines on this specific problem area can be found in the current medical guideline repositories (e.g. Association of the Scientific Medical Societies in Germany [AWMF], Guidelines International Network [GIN]). Recommendations can be found sporadically in guidelines which show a high overlap with the topics of social isolation and loneliness in the elderly. When considering the social environment, for example, the GP guideline "Geriatric Assessment in General Practice" [129] recommends regularly asking geriatric patients whether they have people they can confide in and who could support them in an emergency.

Against the background of the COVID-19 pandemic, the S1 guideline "Social participation and quality of life in inpatient geriatric care under the conditions of the COVID-19 pandemic" [130] has been in existence in Germany since October 2020 and the S1 guideline "Home care, social participation, and quality of life in people in need of long-term care in the context of mobile nursing care under the conditions of the COVID-19 pandemic – living guideline" [131] since February 2021. Both guidelines strongly recommend that, particularly in the circumstances surrounding the COVID-19 pandemic, nursing professionals enable those receiving care to continue fostering social contacts. In March 2021, the Robert Koch Institute's Federal Health Reporting unit published "Older people at the beginning of the COVID-19 pandemic: A scoping review" [132], which is based primarily on international studies and German contributions to the discussion. In view of the limited available data, the authors strongly appealed for more primary research. So far, the Robert Koch Institute's Federal Health Reporting asks only about social support, but not about social isolation and loneliness [133,134].

Since 2015, the NICE has demanded in its Quality Standard QS137 "Mental well-being and independence for older people" that the measurement of social isolation and loneliness be included in health reporting in the United Kingdom and therefore be continuously evaluated [135]. The eponymous guideline NG32 [136] and the NICE guideline "NG22 - Older people with social care needs and multiple long-term conditions" [137] emphasize that professionals in health and social care should support older people with care needs and multiple chronic conditions in maintaining relationships with their friends, family, and community. At the same time, professionals should learn to better identify social isolation and/or loneliness. Furthermore, it should be ensured that treatment plans and care protocols take into account

ordinary activities such as shopping or visits to public facilities outside the home, regardless of whether the older person lives in a nursing home or in their private home, for example.

The UK guidelines as well as the WHO report demonstrate that social isolation and loneliness tend to be managed through the social rather than the medical system. Medical facilities are viewed more as "connector services" [126], where individuals with risk factors for social isolation and loneliness can be identified and referred.

9 Conclusion

For the benefit assessment, 14 randomized controlled trials (RCTs) investigating interventions intended to prevent and treat social isolation and loneliness were analysed. Six studies focused on the evaluation of preventive interventions, while 8 studies investigated interventions with a therapeutic approach. Interventions implemented by volunteers or healthcare or social professionals existed both in the group of prevention studies and the group of therapeutic studies. The examined interventions are very heterogeneous: volunteer visits in private homes, telephone calls/friendships with volunteers, professional-led group programmes, technology training by volunteers, and a Tai Chi Qigong intervention in combination with volunteer health guides. The described interventions had a duration of 1.5 to 12 months. In the majority of studies, the mean age of the study population was between 70 and 80 years. In almost all studies, over 50% of the study population was female, and 1 study was even restricted to women only.

The risk of bias of all included studies was classified as high already at the study level.

None of the included studies investigated adverse effects of the intervention, but all other prespecified outcomes were reported. The number of investigated outcomes ranged from 1 to 16. Four studies reported no statistically significant changes in favour of the intervention for any of their observed outcomes. Two studies reported statistically significant differences in favour of the intervention for the sole investigated outcome. The remaining 8 studies present mixed results.

Out of a total of 10 statistically significant results found in the prevention studies, only 1 outcome was shown to have relevance. Findings are similar for therapeutic studies: out of 9 statistically significant results on different outcomes, 4 were shown to be relevant.

All things considered, the favourable results which were seen in some areas are difficult to interpret due to high risk of bias, unclear power of most studies included in the benefit assessment, and poor reporting quality of the evaluation of complex interventions. From the evidence available for the benefit assessment, no proof or indications can be derived of a certain type of intervention being effective for preventing, reducing, or managing social isolation and loneliness in elderly people. At the same time, however, it is impossible to conclusively determine the investigated interventions to be ineffective because hints of benefit can be derived for 2 types of interventions (volunteer visits in participants' private homes and professional-led group programmes) and 5 outcomes (social support, mortality, anxiety, self-reported health status, and life satisfaction). For instance, hints were found for programmes involving volunteer visits to socially isolated and lonely persons at minimum increasing life satisfaction or reducing anxiety. Further, there is a hint of professional-led social group work increasing social support in persons at risk of isolation and loneliness. There are

hints of professional-led group services reducing mortality and improving self-reported health in socially isolated, lonely persons.

The health economic assessment investigates (a) costs associated with the technology (intervention costs) and (b) comparative health economic studies. The systematic searches found only 2 health economic publications. These are from 2 studies with therapeutic intention which were also included in the benefit assessment. One study published a cost-utility analysis for the volunteer-implemented widow-to-widow programme, and the second performed a cost-cost comparison between the intervention and control groups for a professionally implemented psychosocial group intervention. The intervention costs calculated as part of study implementation amount to currency-converted and inflation-adjusted €574 per person for volunteer home visits. The difference in cost compared with the control group (standard care and information brochure) of currency-converted and inflation-adjusted €-218 was not statistically significant. For the professionally implemented psychosocial group intervention, there was a currency-converted and inflation-adjusted significant cost difference in the amount of €1127 in favour of the intervention group (control group: no intervention). However, this does not include the costs of the group programme reported in the publication, equalling currency-converted and inflation-adjusted €1053 per person. No cost-outcome ratio was determined for the measured outcomes.

Furthermore, when interpreting the health economic results, the different study types, methodological deficits, and the different underlying health systems with corresponding variation in the involved cost parameters must be taken into account. Therefore, no unequivocal conclusions can be drawn regarding the cost-effectiveness of certain forms of interventions for preventing or reducing social isolation and loneliness in elderly people, particularly not for the German healthcare context.

On the basis of the information provided in the 2 publications, the potential intervention costs were calculated for the German context. For volunteer visits (organization and implementation of 10 to 12 home visits per participant), they equalled €246 to €403 per participant, depending on whether supervision was involved. For the professional-led 3-month group programme, mean intervention costs of €434 per participant were calculated.

They were calculated in light of the results of the analyses from ethical, social, organizational, and legal perspectives are based on the systematic analysis of the discussion sections of the publications included in the benefit assessment, other relevant publications from the scoping literature searches, interviews of affected people, and the discussion in a stakeholder workshop. Interventions combating social isolation and loneliness are generally associated with positive connotations, with their “benefit” not necessarily being defined by health-related outcomes but contact with other people being perceived as a success in itself. Social contact is associated in particular with joy, fun, and higher quality of life, and favourable

effects on health are expected as a result. The idea that services must be tailored to needs has been repeatedly emphasized. Needs orientation is related, on the one hand, to specific characteristics of the target group, such as reachability (e.g. “quiet elderly”), sociocultural makeup, special triggers of social isolation and loneliness (e.g. loss of close relatives), or disease-related barriers. Another topic area is the services’ contents. Different mechanisms of action have been discussed: community-building stimuli through group activities, the unburdening, connecting function of confiding in others, particularly people in similar situations, and the targeted reduction of individual psychological barriers and strengthening of self-efficacy in more therapy-oriented settings. Participation of the target group in developing services is believed to promote acceptance and ensure both the authenticity of encounters and fit of intervention content to interests. Otherwise, interventions may exhibit a high dropout rate, rendering them inefficient. On the other hand, differentiating between preventive and therapeutic interventions is deemed of little use, whereas focusing on the severity of impairment would be more useful.

The implementation of interventions must take into account both mental barriers and technical and organizational aspects. The removal of mental barriers can be supported, e.g. by multi-step services, where an initial trust-building phase is followed by a phase with more extensive contacts. Another essential factor in this context is the sustainability of services, which was identified as a critical ethical criterion. Technical and organizational aspects include the reachability of services by (public) transport or any driving services, taking into account any costs incurred, or low-threshold access to services without complex application procedures. Particular challenges result from the large regional variations in services (urban-rural gap), the population being heterogeneous in terms of sociocultural and socioeconomic background, and the difficulties associated with reaching particularly vulnerable population groups. Therefore, different strategies should be followed for the advertising of services. Alongside public communication via local media, bulletin boards, or flyers, which tend to attract the participation of relatively “active” seniors, interventions should employ targeted, if necessary, outreach strategies, e.g. involving general practitioners’ offices, mobile nursing or social services or pharmacies in order to reach more isolated clients who might be in particular need.

Further organizational aspects are infrastructure and staff. Group-based services might take place, e.g. in municipal or neighbourhood centres, elderly assistance facilities, day-care facilities for seniors, libraries, or sports facilities. Services to combat social isolation and loneliness are implemented by both trained professionals, e.g. social workers or nurses, and by volunteers who are typically laypersons with regard to their social work or nursing expertise. With support offerings which are based on reciprocity, members of the target group become active service providers as well. One challenge in this context is ensuring that all involved parties possess adequate qualifications, which are not limited to knowledge of the intervention itself, but also comprise skills such as discussion moderation, group leadership,

social skills, and the handling of vulnerable groups. The recruitment and qualification of volunteers, in particular, can quickly become a hurdle to the implementation of interventions, particularly in regions which tend to be socioeconomically disadvantaged.

From a social law perspective, several options for integrating interventions to combat social isolation and loneliness are already available. Assistance for the elderly, for instance, already offers various interventions to combat social isolation and loneliness in the elderly, e.g. volunteer visiting services and professional-led group programmes. Preventive services may be covered by health insurance funds because social isolation and loneliness in the elderly increases the risk of disease, particularly mental disorders.

Suggestions for the future also include selective contracts as per Section 149a SGB V with long-term care insurance, municipalities, and welfare institutions, which also aim to better integrate the prevention of social isolation and loneliness in the elderly. It is also conceivable to enshrine care and case management in standard care under health insurance law as well as to enshrine a subjective public right to aid in case of social isolation and loneliness in elderly assistance law. This could provide affected people with legally enforceable rights to services even beyond the existing services. For this purpose, elderly assistance law would need to be restructured in such a way that it includes a catalogue of services listing favourably evaluated interventions. This could be modelled after health insurance law, whose concretization concept has implemented the very heterogeneous service prerequisites and service contents in a detailed and subjective legal manner.

Conclusion

In summary, the results of this HTA suggest a need for developing and testing valid and needs-adapted concepts for the prevention and reduction of social isolation and loneliness in elderly people on the basis of the variety of prior publications. The MRC framework for the development of complex interventions offers a framework for doing so. For the first step, the development of a theoretical impact model, prior research done in the studies analysed herein can be used, preferably from studies which found advantages of the intervention groups or hints of benefit at least in part of the observed outcomes. Participatory approaches involving relevant stakeholders are recommended for the modelling of interventions, taking into account affected people's preferences and needs as well as service providers' and volunteers' skills and resources. The planning of the implementation strategy and subsequent feasibility study should be informed by requirements and challenges from ethical, social, organizational, and legal perspectives which were determined in Chapter 6 and should additionally comprise a realistic cost estimate which is valid for the German context. Ultimately, effectiveness must be verified in the context of an RCT which focuses equally on (a) process evaluation, (b) the determination of benefit and harm, including based on the outcome parameters determined in consultation with stakeholders, and (c) cost effectiveness. Transparent documentation of all steps ensures the traceability of the approach and the interpretation of results.

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Please see full HTA report for the full reference list.

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Appendix A– Topics of the EUnetHTA Core Model

The European Network for Health Technology Assessment (EUnetHTA) is a network of European HTA agencies. EUnetHTA promotes the exchange of HTA information between its members and developed the core model [138] for this purpose. IQWiG is also a member of the network.

In order to make it easier for readers of this HTA report to find information on the superordinate domains of the EUnetHTA Core Model, Table 15 indicates where the relevant information can be found. The original names of the domains of the core model are used to describe the topics.

Table 15: Domains of the EUnetHTA Core Model

EUnetHTA domain	**Information in chapters and sections of the HTA report**
Health problem and current use of the technology (CUR)	**Background** Chapter 1
Description and technical characteristics of technology (TEC)	
Safety (SAF)	**Benefit assessment** Section 3.1; Chapter 4
Clinical effectiveness (EFF)	
Costs and economic evaluation (ECO)	**Health economic evaluation** Section 3.2; Chapter 5
Ethical analysis (ETH)	**Ethical aspects** Section 3.3; Section 6.1
Patients and social aspects (SOC)	**Social aspects** Section 3.4; Section 6.2
Legal aspects (LEG)	**Legal aspects** Section 3.4; Section 6.3
Organizational aspects (ORG)	**Organizational aspects** Section 3.4; Section 6.2

Appendix B – Search strategies

B.1 – Search strategies for the benefit assessment

B.1.1 – Searches in bibliographic databases

Search for systematic reviews

1. PubMed

Search interface: NLM

The following filters were adopted:

- Geriatric Medicine: Van de Glind [139] (adaptiert für PubMed)

#	Searches
1	social isolation OR loneliness
2	elderly[tiab] or community-dwelling[tiab] or geriatric[tiab] or "mini-mental state"[tiab] or alzheimer[tiab] or alzheimer's[tiab] or alzheimers[tiab] or mmse[tiab] or caregivers[tiab] or falls[tiab] or adl[tiab] or frailty[tiab] or gds[tiab] or ageing[tiab] or "hip fractures"[tiab] or elders[tiab] or frail[tiab] or mci[tiab] or demented[tiab] or psychogeriatrics[tiab] or "cognitive impairment"[tiab] or "postmenopausal women"[tiab] or comorbidities[tiab] or dementia[tiab] or aging[tiab] or older[tiab] or "daily living"[tiab] or "cognitive decline"[tiab] or "cognitive impairment"[tiab] or residents[tiab] or "cognitive functioning" or "old people"[tiab] or nursing homes[mh] or geriatric assessment[mh] or aging[mh] or frail elderly[mh] or alzheimer disease[mh] or homes for the aged[mh] or cognition disorders[mh] or dementia[mh] or activities of daily living[mh] or aged, 80 and over[mh]
3	#1 AND #2 AND systematic[sb]
4	#3 AND 2010:2020[DP]

2. Health Technology Assessment Database

Search interface: INAHTA

#	Searches
1	("Social Isolation")[mh]
2	("Loneliness")[mh]
3	(isolat* or lonel*)[title]
4	#1 OR #2 OR #3
5	((isolat* or lonel*)[title]) OR ("Loneliness")[mh] OR ("Social Isolation")[mh]) FROM 2010 TO 2020

Search for primary studies

1. MEDLINE

Search interface: Ovid

- Ovid MEDLINE(R) 1946 to January Week 4 2021,
- Ovid MEDLINE(R) Daily Update February 01, 2021

The following filters were adopted:

- RCT: Lefebvre [140] – Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity-maximizing version (2008 revision)

#	**Searches**
1	exp Social Isolation/
2	(loneliness* or social isolation* or well-being* or social support* or social network*).ti.
3	(social isolation* or loneliness* or lonely).ab.
4	or/1-3
5	(Elderly or community-dwelling or geriatric or caregivers or falls or Adl or Frailty or Gds or Ageing or elders or Frail or Psychogeriatrics or postmenopausal women or Comorbidities or senior*).ti,ab.
6	geriatric assessment/ or frail elderly/ or "homes for the aged"/
7	(older adj3 (people or women or men or adults or persons or individuals or subjects)).ti,ab.
8	exp *aged/
9	or/5-8
10	randomized controlled trial.pt.
11	controlled clinical trial.pt.
12	(randomized or placebo or randomly or trial or groups).ab.
13	drug therapy.fs.
14	or/10-13
15	14 not (exp animals/ not humans.sh.)
16	and/4,9,15
17	16 not (comment or editorial).pt.
18	17 and (english or german).lg.
19	exp review/ or meta analysis/ or consensus/ or exp guideline/
20	18 not 19

Search interface: Ovid

- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations 1946 to February 01, 2021
- Ovid MEDLINE(R) Epub Ahead of Print February 01, 2021

#	Searches
1	(loneliness* or social isolation* or well-being* or social support* or social network*).ti.
2	(social isolation* or loneliness* or lonely).ab.
3	(well-being adj9 (older or elderly)).ti,ab.
4	or/1-3
5	(Elderly or community-dwelling or geriatric or caregivers or falls or Adl or Frailty or Gds or Ageing or elders or Frail or Psychogeriatrics or postmenopausal women or Comorbidities or senior*).ti,ab.
6	(older adj3 (people or women or men or adults or persons or individuals or subjects)).ti,ab.
1	(loneliness* or social isolation* or well-being* or social support* or social network*).ti.
2	(social isolation* or loneliness* or lonely).ab.
3	(well-being adj9 (older or elderly)).ti,ab.
4	or/1-3
5	(Elderly or community-dwelling or geriatric or caregivers or falls or Adl or Frailty or Gds or Ageing or elders or Frail or Psychogeriatrics or postmenopausal women or Comorbidities or senior*).ti,ab.
6	(older adj3 (people or women or men or adults or persons or individuals or subjects)).ti,ab.
7	or/5-6
8	(clinical trial* or random* or placebo).ti,ab.
9	trial.ti.
10	or/8-9
11	and/4,7,10

2. Embase

Search interface: Ovid

- Embase 1974 to 2021 February 01

The following filter was adopted:

- RCT: Wong [141] – Strategy minimizing difference between sensitivity and specificity

#	Searches
1	social isolation/
2	loneliness/
3	(loneliness* or social isolation* or well-being* or social support* or social network*).ti.
4	(social isolation* or loneliness* or lonely).ab.
5	or/1-4
6	(Elderly or community-dwelling or geriatric or caregivers or falls or Adl or Frailty or Gds or Ageing or elders or Frail or Psychogeriatrics or postmenopausal women or Comorbidities or senior*).ti,ab.
7	(older adj3 (people or women or men or adults or persons or individuals or subjects)).ti,ab.
8	exp aged/
9	or/6-8

#	Searches
10	(random* or double-blind*).tw.
11	placebo*.mp.
12	or/10-11
13	and/5,9,12
14	13 not medline.cr.
15	14 not (exp animal/ not exp human/)
16	15 not (Conference Abstract or Conference Review or Editorial).pt.
17	16 and (english or german).lg.

3. The Cochrane Library

Search interface: Wiley

- Cochrane Central Register of Controlled Trials: Issue 2 of 12, February 2021

#	Searches
#1	[mh "Social Isolation"]
#2	(loneliness* or social isolation* or well-being* or social support* or social network*):ti
#3	(social isolation* or loneliness* or lonely):ab
#4	#1 or #2 or #3
#5	(Elderly or community-dwelling or geriatric or caregivers or falls or Adl or Frailty or Gds or Ageing or elders or Frail or Psychogeriatrics or postmenopausal women or Comorbidities or senior*):ti,ab
#6	[mh ^"geriatric assessment"] or [mh ^"frail elderly"] or [mh ^"homes for the aged"]
#7	(older NEAR/3 (people or women or men or adults or persons or individuals or subjects)):ti,ab
#8	[mh "Aged"[mj]]
#9	#5 or #6 or #7 or #8
#10	#4 and #9 in Trials
#11	#10 not (*clinicaltrial*gov* or *who*trialsearch* or *clinicaltrialsregister*eu* or *anzctr*org*au* or *trialregister*nl* or *irct*ir* or *isrctn* or *controlled*trials*com* or *drks*de*):so
#12	#11 not ((language next (afr or ara or aze or bos or bul or car or cat or chi or cze or dan or dut or es or est or fin or fre or gre or heb or hrv or hun or ice or ira or ita or jpn or ko or kor or lit or nor or peo or per or pol or por or pt or rom or rum or rus or slo or slv or spa or srp or swe or tha or tur or ukr or urd or uzb)) not (language near/2 (en or eng or english or ger or german or mul or unknown)))

B.1.2 – Searches in study registries

1. ClinicalTrials.gov

Provider: U.S. National Institutes of Health

- URL: http://www.clinicaltrials.gov
- Type of search: Expert Search

Search strategy
(loneliness OR social isolation OR isolation) AND AREA[ConditionSearch] (elderly OR Ageing OR senior OR aged OR older)
AREA[ConditionSearch] Social Isolation

2. International Clinical Trials Registry Platform Search Portal

Provider: World Health Organization

- URL: http://apps.who.int/trialsearch
- Type of search: Standard Search

Search strategy
elderly AND social support OR Ageing AND social support OR senior AND social support OR aged AND social support OR older AND social support OR elderly AND isolation OR Ageing AND isolation OR senior AND isolation OR aged AND isolation OR isolation AND older OR elderly AND loneliness OR Ageing AND loneliness OR senior AND loneliness OR aged AND loneliness OR Loneliness AND older

B.2 – Search strategies for the health economic evaluation

B.2.1Bibliographic databases

1. MEDLINE

Search interface: Ovid

- Ovid MEDLINE(R) ALL 1946 to February 05, 2021

The following filter was adopted:

- Health economic evaluation: Glanville [142] – Emory University (Grady) filter

#	Searches
1	exp Social Isolation/
2	(loneliness* or social isolation* or well-being* or social support* or social network*).ti.
3	(social isolation* or loneliness* or lonely).ab.
4	or/1-3
5	(Elderly or community-dwelling or geriatric or caregivers or falls or Adl or Frailty or Gds or Ageing or elders or Frail or Psychogeriatrics or postmenopausal women or Comorbidities or senior*).ti,ab.
6	geriatric assessment/ or frail elderly/ or "homes for the aged"/
7	(older adj3 (people or women or men or adults or persons or individuals or subjects)).ti,ab.
8	exp *aged/
9	or/5-8
10	(economic$ or cost$).ti.
11	cost benefit analysis/

#	Searches
12	treatment outcome/ and ec.fs.
13	or/10-12
14	13 not ((animals/ not humans/) or letter.pt.)
15	and/4,9,14
16	15 not (comment or editorial).pt.
17	16 and (english or german).lg.

2. Embase

Search interface: Ovid

- Embase 1974 to 2021 February 05

The following filters were adopted:

- Health economic evaluation: Glanville [142] – Embase G

#	Searches
1	social isolation/
2	loneliness/
3	(loneliness* or social isolation* or well-being* or social support* or social network*).ti.
4	(social isolation* or loneliness* or lonely).ab.
5	or/1-4
6	(Elderly or community-dwelling or geriatric or caregivers or falls or Adl or Frailty or Gds or Ageing or elders or Frail or Psychogeriatrics or postmenopausal women or Comorbidities or senior*).ti,ab.
7	(older adj3 (people or women or men or adults or persons or individuals or subjects)).ti,ab.
8	exp aged/
9	or/6-8
10	(cost adj effectiveness).ab.
11	(cost adj effectiveness).ti.
12	(life adj years).ab.
13	(life adj year).ab.
14	qaly.ab.
15	(cost or costs).ab. and controlled study/
16	(cost and costs).ab.
17	or/10-16
18	and/5,9,17
19	18 not medline.cr.
20	19 not (exp animal/ not exp human/)
21	20 not (Conference Abstract or Conference Review or Editorial).pt.
22	21 and (english or german).lg.

3. Health Technology Assessment Database

Search interface: INAHTA

#	Searches
1	"Social Isolation"
2	(loneliness* OR (social isolation*) OR (well-being*) OR (social support*) OR (social network*))[title]
3	((social isolation*) or loneliness* or lonely)[abs]
4	#1 OR #2 OR #3
5	Elderly or (community-dwelling) or geriatric or caregivers or falls or Adl or Frailty or Gds or Ageing or elders or Frail or Psychogeriatrics or (postmenopausal women) or Comorbidities or senior*
6	"geriatric assessment" or "frail elderly" or "homes for the aged" or "Aged"
7	(older AND (people or women or men or adults or persons or individuals or subjects))
8	#7 OR #6 OR #5
9	#4 AND #8